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PROCEEDINGS

Workshop on Standard Setting Processes in the Ontario Ministry of the Environment

Toronto, February 1-2, 1989

Sponsored By
The Standards Steering Committee,
Ontario Ministry of the Environment

Compiled By
The Hazardous Contaminants Coordination Branch,
Ontario Ministry of the Environment

March 1989

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WORKSHOP ON STANDARD SETTING PROCESSES IN THE ONTARIO MINISTRY OF THE ENVIRONMENT

Sponsored by
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TABLE OF CONTENTS

FOREWORD

RECOMMENDATIONS FROM THE STANDARDS STEERING COMMITTEE

OPENING REMARKS — *J.J. SMITH*

LECTURES ON STANDARD SETTING PROCESSES IN THE MINISTRY OF THE ENVIRONMENT.

Listing/delisting processes in waste management	R.K. Khettry
Ambient air standards	G. Nagy
Setting aquatic environmental objectives and guidelines	C. De Barros
Drinking water objectives – an example of federal–provincial co–operation	A. Vajdic
Multimedia standard setting: risk identification	A.C. Socha
Multi–media standard setting: from risk identification to the scientific criteria document	G. Jenkins
Public consultation and the Advisory Committee on Environmental Standards	R.R. Weiler

DISCUSSION GROUP PRESENTATIONS TO THE PLENARY SESSION

Risk identification	A. Vajdic, A.C. Socha
Human risk assessment	A. Szakolcai, B. Leece
Risk assessment in non–human biota	S. Abernathy, K. Johnson
Integrated standard setting and multimedia concerns	B. Thorpe, B.Worthington
Public participation and the Advisory Committee on Environmental Standards	R.R. Weiler, D. Evans

CLOSING REMARKS — *J.J. SMITH, K. ROBERTS*

APPENDIX A: Workshop program

APPENDIX B: List of persons invited to attend

APPENDIX C: Discussion group leaders and rapporteurs.

FOREWORD

The Standard Steering Committee* of the Ministry of the Environment sponsored and organized a workshop on a standard setting processes in the Ministry on February 1 and 2, 1989. About 50 staff from the Ministries of the Environment and of Labour and from the federal Department of Health and Welfare participated. The workshop program and a list of those invited are provided in APPENDICES A and B. The Standards Steering Committee has reviewed and prioritized the recommendations of the workshop. A listing of recommendations for priority attention follow this foreword.

The objectives the workshop were three-fold:

- to increase the understanding among staff of the Ministry's standard setting processes;
- to identify common hurdles and issues; and
- to develop recommendations for Ministry-wide guidelines for harmonizing standard setting processes.

The morning of the first day was taken up by lectures on standard setting processes in the Waste Management, Air Resources, Water Resources and Hazardous Contaminants Coordination Branches and on public consultation and the proposed Advisory Committee on Environmental Standards.

In the afternoon of same day, the participants were grouped into five discussion groups, each headed by a discussion leader and a rapporteur. Their names are given in Appendix C. To ensure effective discussions, the leader and rapporteur, together with additional resource persons, had prepared and distributed beforehand back-ground material on the five discussion topics:

- risk identification;
- risk assessment - humans;
- risk assessment - other organisms;
- integrated standard setting; and
- public consultation in standard setting

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* This committee has representation from the Air Resources, Water Resources, Waste Management and Hazardous Contaminants Coordination Branches and the West-Central Region of the Ministry of the Environment and the Policy and Regulation Branch of the Ministry of Labour.

On the second day, the discussion group leaders reported back to all the participants on the conclusions and recommendations reached by each group. These were discussed and have been summarized for inclusion in these proceedings.

These proceedings, like the workshop itself, are divided into two sections: the presentations and the records of the discussion group considerations. The manuscripts have not been edited but are printed as received from the authors in the interest of distributing the material as rapidly as possible. The Standards Steering Committee wishes to extend its appreciation to the authors of the presentations and to the discussion group leaders and rapporteurs for their efforts in preparing the manuscripts.

The proceedings will serve as record of the activities and discussions of the workshop for participants. The proceedings should not be regarded as representing formal Ministry of the Environment policy.

One of the conclusion of the workshop is that the public needs to be educated about the standard setting processes within the Ministry. Such education would increase the public's understanding and acceptance of the standards the Ministry develops. The first stage of educating the public, it was concluded, is to educate the Ministry staff by articulating the standard setting processes and the advantages and disadvantages of each approach. These proceedings are a step in that direction.

R.R. Weiler
Workshop Organizer
Hazardous Contaminants Coordination Branch
1989-04-05

RECOMMENDATIONS FROM THE STANDARDS STEERING COMMITTEE

These workshop proceedings were reviewed and discussed by the SSC at its April 17th, 1989 meeting. Discussion leaders were invited to this session of the SSC to present the Workshop deliberations, highlighting and where possible, prioritizing the recommendations that were made. The SSC has identified the following recommendations for priority attention:

I. Development of an MOE Risk Assessment Policy

It was agreed that development of a consistent assessment policy was a priority need for MOE. This policy should address the following scientific considerations:

(i) a review of classification schemes for carcinogencity;

(ii) guidelines for ADI/uncertainty factor and quantitive risk assessment approaches;

(iii) the question of the use and size of uncertainty factors;

(iv) use of mathematical models for risk assessment and priority setting;

Action: An action plan for the development of an MOE risk assessment policy has been prepared by the SSC. A framework for policy development is to be established via committee by October, 1989. The process will involve review of a discussion paper on an MOE risk assessment policy recently prepared by ARB and HCCB.

II. Consolidation of Risk Identification of Hazardous Substances

It was agreed the MOE should develop a master list of all substances under review by MOE, for the purposes of identifying initiatives across the ministry on a per substance basis.

Action: MOE's Priority Substances Advisory Committee will be requested to act on this.

III. Coordination of MOE Standards Development Activities

It was agreed that a key function of the Standards Steering Committee is to continue to coordinate MOE standards development activities. At this time, key consideration should be given to:

(i) development of a formal Ministry policy on the multimedia approach to standard setting;

(ii) examination and definition of the various stages of the standards setting process, specifically the risk identification, risk assessment and the risk management stages;

(iii) the need to communicate the Ministry's various standard setting processes both internally and to the public; and

(iv) the need to review MOE activities within the area of risk assessment for terrestrial animals.

Action:
- HCCB to develop policy for (i) in 1989/90.
- SSC to review (ii), (iii), and (iv) for future assignment upon completion of Recommendation I.
- (iv) to be partially achieved through the policy development initiative of Recommendation I.
- Communication to public achievable via formation of the Advisory Committee on Environmental Standards (ACES).

J.J. SMITH

OPENING REMARKS

OPENING REMARKS BY:

J.J. SMITH

CHAIRMAN

STANDARDS STEERING COMMITTEE

HAZARDOUS CONTAMINANTS COORDINATION BRANCH

GOOD MORNING, FELLOW COLLEAGUES:

I AM YOUR CHAIRMAN FOR TODAY'S SESSION, AND I WOULD LIKE TO OFFER A FEW WORDS ON WHY YOU ARE HERE, WHAT YOU CAN EXPECT TO ACCOMPLISH OVER THE NEXT TWO DAYS, AND WHAT WILL BE DONE WITH THE RESULTS OF YOUR DELIBERATIONS.

YOUR PRESENCE HERE TODAY REFLECTS THE PLANNING EFFORTS OF THE MINISTRY'S STANDARDS STEERING COMMITTEE, THE BROAD OBJECTIVE OF WHICH, IS IMPLIED BY ITS NAME. THE MEMBERS ARE JOHN RALSTON AND KEN ROBERTS FROM THE WATER RESOURCES BRANCH; CHESTER DUNCAN, UP TO THE END OF 1988*, AIR RESOURCES BRANCH; JIM STOPPS, UP TO THE END OF 1988 AND REPLACED BY ED MCCLOSKEY, FROM THE MINISTRY OF LABOUR; RAJ KHETTRY WITH THE WASTE MANAGEMENT BRANCH, AND MYSELF, FROM THE HAZARDOUS CONTAMINANTS COORDINATION BRANCH.

THE OBJECTIVES OF THE WORKSHOP ARE THREE-FOLD. THE FIRST INVOLVES THE NETWORKING OF STAFF RESPONSIBLE FOR ENVIRONMENTAL STANDARD SETTING. ATTENDEES HERE TODAY REPRESENT MOE'S AIR, WATER, WASTE AND HAZARDOUS CONTAMINANTS COORDINATION BRANCHES, AND THE MINISTRY'S REGIONS. IN ADDITION, COLLEAGUES FROM OUR SISTER MINISTRY, THE MINISTRY OF LABOUR AND A REPRESENTATIVE FROM HEALTH & WELFARE CANADA WERE ALSO INVITED DUE TO THEIR INTEGRAL PART IN MOE'S DEVELOPMENT OF STANDARDS AND GUIDELINES. THE SECOND AND THIRD OBJECTIVES PERTAIN TO HARMONIZATION AND INTEGRATION OF PROCESSES. IT IS AT THIS POINT I WOULD TURN THE PRESENTATION OVER TO DAVID BALSILLIE AND WALTER GILES, BUT UNFORTUNATELY, THEY WERE BOTH CALLED AWAY AT THE LAST MINUTE AND GIVE THEIR REGRETS. HOWEVER, EARLY LAST EVENING, I SPOKE TO THEM, AND THEY DID ASK ME TO SHARE THEIR THOUGHTS WITH YOU ON THE MATTER.

* REPLACED BY MS HELLE TOSINE, ASSISTANT DIRECTOR, AIR RESOURCES BRANCH; RAY STEWART FROM THE REGIONS

THEY HAVE THREE MAJOR CONCERNS:

THE FIRST CONCERN PERTAINS TO THE LARGE NUMBER OF PROCESSES WE HAVE CURRENTLY IN PLACE TO DEVELOP STANDARDS, OBJECTIVES, CRITERIA GUIDELINES AND POLICIES. THESE INCLUDE:

- AMBIENT AIR STANDARDS, GUIDELINES, PROVISIONAL GUIDELINES
- EMISSION LIMITS, DISCHARGE LIMITS
- AIR POLLUTION INDEX
- POLICIES FOR INCINERATION
- PROVINCIAL WATER QUALITY OBJECTIVES
- DRINKING WATER OBJECTIVES
- SEDIMENT GUIDELINES
- SPORTS FISH ADVISORIES
- LAKEFILLING GUIDELINES
- DECOMMISSIONING GUIDELINES
- DREDGATE GUIDELINES
- SLUDGE AND WASTE UTILIZATION GUIDELINES FOR AGRICULTURAL PURPOSES
- "UPPER LIMITS OF NORMAL" FOR VEGETATION AND SOIL
- WASTE LISTING/DELISTING PROCESS
- GUIDELINES FOR THE MANAGEMENT OF PESTICIDES
- MULTI-MEDIA GUIDELINES
- PROCESS MONITORING LIMITS, E.G., OPACITY/COLOR, TEMPERATURE

- OTHER LEGAL INSTRUMENTS TO WHICH LIMITS ARE ADDED INCLUDE:
  - CERTIFICATES OF APPROVAL
  - CONTROL ORDERS

- IN ADDITION, WE ALSO ENFORCE FEDERAL STATUTES.

THIS LARGE NUMBER OF LIMITS, WHICH ON THE SURFACE APPEAR TO BE UNRELATED, CREATE CONFUSION FOR THE PRIVATE SECTOR PLUS OUR PUBLIC SECTOR COLLEAGUES AND EVEN YOUR ADMS.

THE SECOND CONCERN RELATES TO KEEPING ABREAST OF AN EXPLODING DATABASE OF INFORMATION RELATING TO THE INCREASING NUMBER OF CHEMICALS DETECTED IN THE ENVIRONMENT AND INCREASING INFORMATION ON CHEMICAL EFFECTS AND ENVIRONMENTAL FATE.

DESPITE ALL OF THIS INFORMATION WE STILL HAVE A TREMDENDOUS NUMBER OF DATAGAPS WHICH MAKES IT DIFFICULT TO SET STANDARDS.

THE THIRD CONCERN RELATES TO RISING PUBLIC EXPECTATION. DIMENSIONS OF THIS CONCERN ARE CHARACTERIZED BY:

- A GREATER PUBLIC KNOWLEDGE AND AWARENESS;
- SKEPTICISM ABOUT GOVERNMENT AND INDUSTRY;
- CONCERNS ABOUT HEALTH, ENVIRONMENT AND QUALITY OF LIFE; AND
- QUESTIONS ON HOW CLEAN IS CLEAN?, WHAT IS SAFE?, WHAT IS ACCEPTABLE?

DAVID AND WALTER RAISED A NUMBER OF ISSUES THAT I SHOULD PROVIDE FOR DISCUSSION PURPOSES. IN BRIEF, THESE INCLUDE:

- THE NEED FOR LEGALLY DEFINED STANDARDS OR CHALLENGABLE OBJECTIVES;
- THE CONCEPT OF ADOPTION BY REFERENCE OF OTHER JURISDICTIONS' STANDARDS;
- THE NEED FOR A SHORT TURN AROUND TIME FOR CERTIFICATES OF APPROVAL;
- THE QUESTION OF WHERE WILL THE TOXICOLOGICAL DATA COME FROM; AND

° DEVELOPMENT OF A RISK ASSESSMENT POLICY
  - SHOULD WE DO IT?
  - CAN WE DO WITHOUT IT?
  - POLITICAL DOWNSIDES?
  - PACKAGING?

HOWEVER, DAVID AND WALTER POINTED OUT THAT OUR ENDEAVOURS MUST BE:

° SCIENTIFICALLY VALID.
° LEGALLY SOUND; AND
° INTELLECTUALLY HONEST.

FURTHERMORE, THEY INSISTED THAT OUR DELIBERATIONS MUST INCLUDE:

1. A SERIOUS REVIEW OF OUR PROCESSES;
2. IDENTIFYING AREAS FOR INTERNAL INTEGRATION, AND
3. IDENTIFYING THE POSSIBILITY OF FORMING EXTERNAL PARTNERSHIPS.

WITH RESPECT TO FOLLOW UP FROM OUR TWO DAYS OF DELIBERATIONS, THE REPORT ON THE WORKSHOP AND RECOMMENDATIONS WILL BE PROVIDED TO THE STANDARDS STEERING COMMITTEE FOR THEIR DISCUSSION AND DEVELOPMENT OF IMPLEMENTATION STRATEGIES.

IN CLOSING, I WOULD LIKE TO LEAVE YOU WITH A SHORT STORY THAT I HEARD THE OTHER DAY, NOT FROM THE OFFICES OF CONRAD DEBARROS OR KAREN JOHNSON, BUT AT A LECTURE ON ORGANIZATIONAL BEHAVIOUR, DESCRIBING HOW MANY ORGANIZATIONS CONDUCT THEIR BUSINESS TODAY, AND HOW SOME OF US HAVE WORKED TOGETHER IN THE 80'S.

TWO INDIVIDUALS* WERE HIKING IN BEAUTIFUL NORTHERN ONTARIO. THE ONE ADMIRES THE PURITY AND CLARITY OF THE WATER THAT HE HAS HELPED TO PROTECT, THE OTHER TAKES GREAT PRIDE IN THE CLEAN FRESH AIR, AS

* COULD BE DIRECTORS, ADMS OR STANDARD SETTERS

A RESULT OF HIS EFFORTS BACK AT THE OFFICE. AS THEY CONTINUE, THEY COME TO A CLEARING, AND SUDDENLY, OUT OF THE BUSH, APPEARS ONE OF THE MEANEST, BIGGEST, BLACK BEARS IN ALL OF NORTHERN ONTARIO. BEING TRAINED IN ADVANCED CIVIL SERVICE SURVIVAL TACTICS, THEY IMMEDIATELY FREEZE. THEN THE ONE INDIVIDUAL, I DON'T RECALL IF HE IS FROM AIR OR WATER, MOVES VERY SLOWLY OVER TO THE NEAREST LOG. HE CAREFULLY UNLACES HIS HIKING BOOTS, REMOVES THEM, AND VERY SLOWLY OPENS UP HIS KNAPSACK AND TAKES OUT A PAIR OF BROOKS RUNNING SHOES, AND PUTS THEM ON. THE OTHER INDIVIDUAL WHO IS STILL STANDING THERE IN A FROZEN STATE, SAYS "THERE'S NO WAY YOU'RE GOING TO OUTRUN THAT BEAR!" THE INDIVIDUAL IN THE RUNNING SHOES SAYS IN REPLY "I DON'T HAVE TO OUTRUN THAT BEAR, I ONLY HAVE TO OUTRUN YOU!"

FOR THE NEXT TWO DAYS, AT LEAST I ASK PLEASE DON'T LEAVE YOUR COLLEAGUES TO THE BEARS.

I NOW PASS YOU OVER TO ROLAND WEILER FOR A FEW WORDS ON ADMINISTRATIVE PROCEDURES.

THANK YOU.

LECTURES ON STANDARD SETTING PROCESSES IN THE MINISTRY OF THE ENVIRONMENT

R.K. KHETTRY

LISTING/DELISTING PROCESSES IN WASTE MANAGEMENT

WORKSHOP ON STANDARD SETTING PROCESSES
(February 1-2, 1989, Ibis Hotel, Toronto)

Summary: Listing/Delisting processes
in Waste Management.

Speaker: R.K. Khettry, Waste Management Branch.

INTRODUCTION

In order to ensure proper handling and disposal of wastes, Regulation 309 of the Environmental Protection Act provides definitions of hazardous wastes, and details the requirements for generators, carriers and receivers with respect of waste registration and manifesting.

The classification of hazardous wastes is achieved by a listing/testing approach, whereby wastes are defined as hazardous either by being listed in a Schedule of the Regulation, or because of specified hazardous characteristics normally determined by test protocols.

The Regulation allows for review and continual updating of the Schedules. New wastes judged to be hazardous are added to the lists, while specific wastes from a particular facility determined to be non-hazardous can be reviewed (or delisted).

LISTING PROCESS

Hazardous wastes are listed in Schedule 1 and Schedule 2 because they typically exhibit one or more of the hazardous characteristics or because they contain contaminants that are known to be toxic or otherwise hazardous to human health and the environment. The purpose of listing a waste as hazardous is to ensure that the generator will identify and manage the waste properly.

The listing process is based on the evaluation of the potential hazard of the waste on human health or the environment. The evaluation relies on toxicity criteria and environmental behaviour criteria of the waste. The process commences with the preparation of a listing document which must address the following issues:

1) identification and detailed information about the process and the industrial sector responsible for the generation of the waste in question;

2) determination of the waste constituents, their concentration and their toxic effect levels;

3) discussion of the benefits of listing the waste, compared to the existing waste management practices;

4) impact on the environment and/or health, if this waste is not listed.

The hazardousness of a waste is defined in terms of hazardous characteristics, environmental behaviour criteria and toxicity criteria.

Any wastes exhibiting one of the following hazardous characteristics may be listed in the Regulation:

1) ignitable
2) corrosive
3) reactive
4) leachate toxic.

A number of environmental behaviour criteria must also be evaluated:

1) environmental transport (migration of the chemicals in the waste through environmental media);

2) environmental persistence (tendency of a chemical to resist degradation under environmental stresses);

3) bio-accumulation (tendency for a chemical to accumulate in biological systems);

4) environmental exposure (possible pathways through which the waste contaminants can reach a receptor and adversely affect human health and the environment).

There are a number of toxicity criteria which identify the level of toxicity and potency of individual chemicals in the waste:

1) acute lethality
2) sublethal phytotoxicity
3) sublethal non-mammalian toxicity
4) sublethal mammalian toxicity
5) teratogenicity
6) mutagenicity
6) carcinogenicity

The environmental behaviour criteria and the toxicity criteria are evaluated for a specific waste, using a method derived from the Vector Scoring System developed by MOE. The Vector Scoring System scores a specific chemical on a scale of 0 to 10, for specific criteria. A screening process, established specifically for hazardous waste evaluation, identifies target chemicals for detailed evaluation by MOE.

The listing document is reviewed by members of the WMB and the Hazardous Waste Review Committee (HWRC) (internal committee within the Ministry of the Environment). Through recommendation of the WMB director, the listing document is reviewed by an external Hazardous Waste Review Advisory Committee (HWAC), who will undertake public consultation and finally make recommendation to the Minister of the Environment to list (or not list) the waste of concern. The listing process is completed once Regulation 309 is amended.

DELISTING PROCESS

For a review (or delisting) of wastes from the Schedules the applicant must address, by means of a comprehensive sampling, testing and reviewing program, the following issues:

1) that the waste in question does not meet any of the criteria for which the waste was originally listed;

2) additional information regarding other hazardous properties or other constituents present in the waste at significant levels;

3) other potential impacts of the waste on specific site, on alternative waste disposal facilities and provincial waste management practices.

The toxicity criteria used in the evaluation of the delisting application are the same ones as the ones used in the listing process. The application is also reviewed by the same groups and committees as in the listing process.

G. NAGY

AMBIENT AIR STANDARDS

AMBIENT AIR STANDARDS

GEORGE NAGY AIR STANDARDS COORDINATOR

I. LEGISLATION

THE ENVIRONMENTAL PROTECTION ACT IN SECTION 8 MANDATES THE CERTIFICATE OF APPROVAL PROGRAM. (C OF A PROGRAM).
ONTARIO REGULATION 308, UNDER THE ENVIRONMENTAL PROTECTION ACT PROVIDES POINT OF IMPINGEMENT 0.5 H STANDARDS FOR 100 AMBIENT AIR CONTAMINANTS, AND MOST IMPORTANTLY, SPECIFIES THE WAY IN WHICH THESE NUMBERS ARE TO BE USED BY PROVIDING A COMPUTATIONAL PROCEDURE BASED ON THE PHYSICS AND MICROMETEROLOGY OF DISPERSION TO EVALUATE THE APPLICATIONS FOR APPROVALS (C OF A'S). MENTIONED ABOVE, TO GRANT OR DENY PERMITS FOR INDUSTRIAL AND OTHER FACILITIES WHICH INTEND TO EMIT AMBIENT AIR CONTAMINANTS.

IT CAN BE SEEN FROM THE ABOVE THAT THE C OF A PROGRAM RELIES HEAVILY ON THE 100 STANDARDS OF O R 308. HOWEVER IT WAS OBVIOUS FROM THE VERY BEGINNING OF THE APPEARANCE OF O R 308 THAT THE 100 STANDARDS WOULD NOT COVER EVERY CASE. NEW COMPOUNDS NOT USED IN ONTARIO UP TO THAT POINT IN TIME APPEARED CONSISTENTLY ON NEW C OF A APPLICATIONS FILED, AND THE AIR RESOURCES BRANCH HAD TO DEVELOP A PROCESS FOR CREATING NEW AMBIENT AIR STANDARDS - A CASE OF NECESSITY BEING THE MOTHER OF INVENTION. THE NEW STANDARDS HAD TO BE AVAILABLE WITHIN A RESONABLE TIME FOLLOWING THE APPLICATION FOR THE C OF A, AND THEY HAD TO BE REASONABLE FROM THE ENVIRONMENTAL POINT OF VIEW. DURING THE PAST

20 YEARS IT MAY BE SAID THAT AMBIENT AIR STANDARDS WERE DEVELOPED IN TIME AND C OF A APPLICANTS LARGE AND SMALL COULD BE SATISFIED.

DEVELOPMENT OF THE PROCESS FOR SETTING AMBIENT AIR STANDARDS

THE ENGINEERS IN THE MANAGEMENT GROUP AT THE TIME IN THE AIR RESOURCES BRANCH, DEVELOPED THE PROCESS THAT IS ESSENTIALLY ONLY NOW BEING REVISED - I.E. THE 308 REVISION PROJECT. THE PHILOSOPHY DEVELOPED AT THE TIME WAS BASED ON EFFECTS, THE POINT BEING THAT THE AMBIENT AIR STANDARDS WERE SET AT THE LOWEST CONCENTRATION AT WHICH AN ADVERSE EFFECT WAS FOUND ON HEALTH, VEGETATION (CROPS), WILDLIFE, MATERIALS, QUALITY OF LIFE (ODOUR), SOILING, CORROSION, OR ANY OTHER EFFECT WITH AN IMPACT ON MAN OR THE ENVIRONMENT. THIS CAME TO BE CALLED THE LIMITING EFFECT PHILOSOPHY. IN DEVELOPING RATIONALES FOR THE NUMERICAL VALUES OF THE STANDARDS IN O R 308 THE ARB TURNED TO MEDICAL EXPERTISE TO JUSTIFY THE NUMBERS BASED ON HEALTH AND THIS IS STILL THE FIRST STEP IN THE DEVELOPMENT OF AMBIENT AIR STANDARDS TODAY. THE MEDICAL EXPERTISE IS OBTAINED FROM THE MINISTRY OF LABOR'S POLICY AND REGULATIONS BRANCH, HEALTH STUDIES SERVICE. AS TO THE FORM THAT THE DEVELOPMENT OF STANDARDS TOOK - WE KNOW THAT A RUDIMENTARY FORM OF THE ENVIRONMENTAL AIR STANDARDS SETTING COMMITTEE OR EASSC WAS FUNCTIONING AT THE TIME. UNFORTUNATELY MINUTES OF MEETINGS AND OTHER RECORDS IN SIGNIFICANT QUANTITTIES APPEAR ONLY AFTER 1983.

THE NUMERICAL VALUES IN O R 308 WERE DEVELOPED IN THIS AD HOC MANNER USING THE OPINIONS OF MEDICAL AND OTHER EXPERTS AND THESE

NUMBERS ARE EMBODIED AS AMBIENT STANDARDS IN THE O R 308 OF TODAY.

I WOULD NOW LIKE TO DESCRIBE ANOTHER SET OF NUMBERS PROMULGATED UNDER THE EPA AS ONTARIO REGULATION 872/74 , PROMULGATED ABOUT THE SAME TIME AS O R 308 WHOSE ORIGINAL VERSION WAS CALLED O R 873/74. O R 872/74 CONTAINS 23 DESIRABLE AMBIENT AIR QUALITY CRITERIA. (AAQC) ACTUALLY PROMULGATED ON 31 OCT 1974 AND FILED IN THE GAZETTE OF NOV 13 1974. THESE NUMBERS DO NOT HAVE THE FORCE OF LAW: THAT IS, THE MODE OF MEASUREMENT OR A COMPUTATION PROCESS IS NOT GIVEN AS IN THE CASE OF O R 308. THE PURPOSE OR PHILOSOPHY BEHIND 872/74'S AAQC'S IS TO ALLOW THE ASSESSMENT OF AMBIENT AIR QUALITY - TO CHECK HOW THE C OF A PROGRAM IS SUCCEEDING IN ROLLING BACK BAD AIR QUALITY. VERY SOON AFTER THE APPEARANCE OF 872/74 THE NEED FOR SPECIFYING THE MEANS OF SAMPLING AND ANALYSIS I.E. THE THE PROBLEM OF SPECIFYING THE METHODS TO BE USED IN THE MEASUREMENTS OF THE VALUES SPECIFIED IN 872/74 BECAME VERY APPARENT, IN FACT THE HAM COMMISSION, SPECIFICALLY RECOMMENDED THAT THESE METHODS BE SPECIFIED SO THAT POLLUTERS, ENVIRONMENTALISTS AND INTERESTED PARTIES AS WELL AS THE MOE WOULD BE USING THE SAME MEASURING STICK TO MEASURE AMBIENT AIR POLLUTION. IN RESPONSE TO THE HAM COMMISSION RECOMMENDATION THE AIR RESOURCES BRANCH SET UP WHAT BECAME THE SUBCOMMITTE ON AMBIENT MEASUREMENTS, WHICH WAS MANDATED TO WRITE DOWN THE APPROVED PROCEDURES FOR THE SAMPLING AND DETERMINATION OF AMBIENT AIR CONTAMINANTS FOR WHICH THE MOE HAD STANDARDS AS IN 308 OR CRITERIA AS IN 872/74. IN HINDSIGHT IT IS NOW EASY TO SEE THAT THIS HAD TO BE DONE BECAUSE OF THE PROLIFERATION OF METHODS AND INSTRUMENTS

AVAILABLE OR RAPIDLY BECOMING AVAILABLE AT THE TIME FROM OFF THE SHELF, FROM CONSULTANTS AND FROM THE AFFECTED INDUSTRIES. IN DUE COURSE THIS SUBCOMMITTE DEVELOPED THE PHILOSOPHY OF WRITING DOWN THE PROCEDURES THAT REFLECTED THE PRACTICES OF THE LABORATORY SERVICES BRANCH CHEMISTS. THIS SUBCOMMITTE IS NOT AS ACTIVE AT THE PRESENT AS FORMERLY AND COMMITTEMENTS HAVE BEEN MADE BY THE ARB MANAGEMENT TO ALLOW IT TO BECOME MORE ACTIVE. THE LATEST PROCEDURE WRITTEN BY THE SUBCOMMITTE IS MOE- AMP #143 ON ODOUR IMPACT MODELS. A SET OF ALL THE PROCEDURES WRITTEN BY THE SUBCOMMITTE IS AVAILABLE RIGHT HERE FOR YOUR INSPECTION OR YOU MAY OBTAIN COPIES FROM THE ARB.

SUMMARY OF WHAT WAS PRESENTED SO FAR:

AMBIENT AIR STANDARDS ARE MANDATED IN TWO REGULATIONS UNDER THE EPA; O R 308 AND O R 872/74.

THE FACT THAT ONLY 100 STANDARDS ARE SPECIFIED IN O R 308 AND ONLY 23 AMBIENT AIR QUALITY CRITERIA IN 872/74 IMPLY OR VOUCHSAFE THE NEED FOR THE SETTING UP OF A PROCESS FOR DEVELOPING ADDITIONAL STANDARDS OR CRITERIA, AND THE AIR RESOURCES BRANCH DID DEVELOP THE PROCESS FOR SETTING ADDITIONAL AMBIENT AIR STANDARDS AS REQUIRED.

II. THE PROCESS FOR SETTING AMBIENT AIR STANDARDS

1. THE REQUEST FOR A STANDARD COMES 90% OF THE TIME FROM THE APPROVALS BRANCH OF THE MOE. AN APPLICATION FOR A CERTIFICATE OF APPROVAL IS FILED BY AN IDIVIDUAL OR A CORPORATION OR THE AGENT THEREOF FOR WHAT IN EFFECT IS A PERMIT TO EMIT A SPECIFIED QUANTITY OF ONE OR MORE AMBIENT AIR CONTAMINANTS. THESE ARE

CHEMICAL COMPOUNDS OR MIXTURES. A COMPLETE DEFINITION OF WHAT IS A CONTAMINANT MAY BE FOUND IN THE EPA. AS POINTED OUT AT THE BEGINNING, THE LANGUAGE OF THE EPA IS VERY CLEAR ON THE LEGAL REQUIREMENT TO FILE AN APPLICATION.

2. THE C OF A APPPLICATION REACHES ONE OF THE APPROVALS EXAMINERS LOCATED AT ONE OF THE REGIONAL OFFICES OF THE MINISTRY OR THE CENTRAL APPROVALS OFFICE, NOW AT 250 DAVISVILLE AND THE APPLICATION IS EXAMINED FOR COMPLIANCE

2.1 AT THIS POINT THE FIRST THING THE EXAMINER DOES (OR SHOULD DO) IS TO SEE IF THE CONTAMINANT/S FEATURED IN THE PROCESS IS OR IS NOT ON THE LIST OF STANDARDS AT THE BACK OF O R 308 OR ON THE LIST ISSUED BY THE ENVIRONMENTAL AIR STANDARDS SETTING COMMITTEE (EASSC). (THIS LIST WILL BE DESCRIBED IN THE COURSE OF THIS PRESENTATION)

2.1.1 IF THE CONTAMINANT/S APPEAR ON EITHER LIST, THE EXAMINER WILL RUN THE PRESCRIBED DISPERSION EQUATION ON A MINICOMPUTER. THE SELECTION OF THE EQUATION DEPENDS ON THE ENGINEERING ASSESSMENT AND STUDY BY THE EXAMINER OF O R 308 AND THE ENGINEERING DETAILS OF THE PROCESS DESCRIBED ON THE APPLICATION. COMPLIANCE IN MOST CASES WILL DEPEND ON THE SOLUTION OF THE DISPERSION EQUATION, WITH THE VALUE FOR THE STANDARD (I.E. THE VALUE FOR THE 0.5H POI SUBSTITUTED ON THE LEFT HAND SIDE OF THE EQUATION AND VARIOUS PROCESS PARAMETERS SUBSTITUTED FOR THE APPROPRIATE QUANTITITES ON THE RIGHT HAND SIDE. IN A TYPICAL CASE THESE PROCESS PARAMETERS ARE; Q - THE EMISSION RATE OF THE CONTAMINANT IN G/S, D -THE STACK DIAMETER, HS THE PHYSICAL STACK

HEIGHT, VS - THE VELOCITY OF GAS STREAM CARRYING THE CONTAMINANT, AND THE LOCAL WIND SPEED WHICH IN MOST CASES IS ASSUMED TO BE 5 M/S. THERE ARE MANY ADDITIONAL ENGINEERING DETAILS TO LOOK UP AND STUDY AND IN COMPLEX CASES THE SERVICES OF AN AIR POLLUTION DISPERSION MODELLING EXPERT MAY HAVE TO BE USED. AT ANY RATE SOLUTION OF THE EQUATION ALLOWS THE EXAMINER TO DECIDE ON THE APPLICATION, ALL OTHER CRITERIA BEING SATISFIED. AS TO JUST WHAT THESE CRITERIA ARE - A THOROUGH ANSWER CAN ONLY BE GIVEN BY ONE OF THE CONSULTANTS FOR AIR AT THE APPROVALS BRANCH WHO HAS STUDIED THE INDIVIDUAL APPLICATION.

2.1.2 IF THE CONTAMINANT/S DO NOT APPEAR ON ANY LIST THE APPLICANT IS INFORMED (OR SHOULD BE INFORMED THAT THERE WILL BE A DELAY WHILE THE STANDARD/S ARE DEVELOPED), AND THE STANDARDS COORDINATOR IS REQUESTED TO DEVELOP AMBIENT AIR STANDARD/S.

2.1.2.1 THE REQUEST FOR STANDARD/S SHOULD BE IN WRITING. THE APPROVALS BRANCH HAVE DEVELOPED AN APPROPRIATE FORM WHICH THE EXAMINING ENGINEER PASSES TO ONE OF THE AIR CONSULTANTS (AT THE PRESENT - JAN 89, THE CONSULTANTS FOR AIR ARE P. DEANGELIS AND S. BELL), WHO CHECK THE RELEVANT DETAILS SUCH AS THE GLC COMPUTATION AT THE POINT OF IMPINGEMENT, THE EMISSION RATE, THE NATURE OF THE RECEPTOR AREA -AS TO POPULATION EXPOSURE, CHARACTER - I.E. URBAN RURAL, INDUSTRIAL, PRESENCE OF SENSITIVE RECEPTORS, ETC. AND FOR THE COMPLETE SPECIFICATION OF THE CHEMICAL COMPOUND/S WHICH CONSTITUTE THE AMBIENT AIR CONTAMINANT. THESE SPECIFICATIONS INCLUDE (SHOULD INCLUDE): MOLECULAR WEIGHT, MOLECULAR FORMULA, NAME AND SYNONYMS, CAS #, PHYSICAL PROPERTIES SUCH AS MELTING POINT, BOILING POINT, VAPOR PRESSURE VS TEMPERATURE FUNCTION,

DENSITY; COMPOSITION IF A MIXTURE, AND WHATEVER CHEMICAL PROPERTIES AND TOXIC PROPERTIES ARE KNOWN.

2.1.2.2 THE LATTER PART OF THE ABOVE PARAGRAPH HAS GENERATED SO MANY QUESTIONS, MEETINGS, AND PROBLEMS THAT I WOULD LIKE TO EXPAND ON THE IMPORTANCE OF PROVIDING THE MAXIMUM POSSIBLE AMOUNT OF INFORMATION RIGHT AT THIS POINT IN THE STANDARD SETTING PROCESS: THE DIFFICULTIES ARISE BECAUSE THE APPLICANT HIMSELF/HERSELF MAY NOT HAVE BEEN AWARE OF THE NEED TO FILE UNTIL A FEW DAYS BEFORE FILING. HE/SHE MAY BE A MANAGER OF A BRANCH PLANT WHICH IS AN EXACT COPY OF A FOREIGN INSTALLATION OR THE MATERIALS USED IN THE PLANT MAY BE IMPORTED PROPRIETARY COMPOUNDS WHOSE COMPOSITION IS UNKNOWN TO THE USER. THE LATTER SITUATION IS COMMON, OFTEN THE ONLY WAY TO FIND OUT A COMPOSITION IS TO CONDUCT LENGTHY NEGOTIATIONS WITH THE MANUFACTURER IN THE U.S. THE LACK OF KNOWLEDGE CAN LEAD TO A SITUATION WHERE THE MOL WILL AGREE TO THE DEVELOPMENT OF A SITE SPECIFIC STANDARD FOR THE PLANT IN QUESTION - THIS APPROACH WAS IN FACT USED FOR SEVERAL COMPUTER CHIP MANUFACTURERS

3. THE NEXT STEP IN THE PROCESS IS TO STUDY THE REQUEST FOR THE STANDARD AND BEGIN THE APPROPRIATE COORDINATION PROCESS COVERING THE VARIOUS EFFECTS ON HEALTH, VEGETATION, MATERIALS, AND QUALITY OF LIFE -(ODOUR).

3.1 THE FIRST OF THESE, HEALTH, REQUIRES THE COMPOSITION AND TRANSMISSION OF THE REQUEST TO THE MOL. IT IS AT THIS STAGE THAT LACK OF KNOWLEDGE OF DETAILS MENTIONED ABOVE ABOUT THE PROPERTIES OF THE CHEMICAL COMPOUNDS BECOMES A CRITICAL BOTTLENECK BECAUSE THE MOL'S SCIENTISTS ARE HIGHLY QUALIFIED, SOME WITH MEDICAL

DEGREES, WHO SHOULD NOT HAVE TO SPEND THEIR TIME LOOKING UP VAPOR PRESSURE FUNCTIONS IN HANDBOOKS. NEVERTHELESS THERE ARE PERIODS WHEN C OF A APPLICATIONS ARRIVE SO RAPIDLY AND IN SUCH VOLUME THAT, ROUTINE SEARCH CANNOT BE THE DONE AT THE ARB AND A LITERATURE SEARCH REQUEST IS MADE - USUALLY TO THE HCC BR., AND THE REQUEST IS TRANSMITTED TO THE MOL. THE MOL ALWAYS HAS THE OPTION OF RETURNING THE REQUEST INDICATING THE NEED FOR MORE INFORMATION OR THE SUGGESTION THAT THE SPECIAL APPROACH BE EMPLOYED, WHICH GENERALLY INVOLVES THE ARRANGEMENT OF A VIST TO THE FACILITY.

3.2 OTHER EFFECTS: FOR EFFECTS ON VEGETATION OR CROPS OR AGRICULTURAL ACTIVITY IN GENERAL THE CONTAMINANT IS REFERRED TO THE PHYTOTOXICOLOGY SECTION OF THE ARB FOR AN OPINION. THE OPINION NORMALLY TAKES THE FORM OF A FORMAL RATIONALE DOCUMENT WITH EXTENSIVE DOCUMENTATION IF THE PHYTO SECTION FEELS THAT THE CONTAMINANT IS OF INTEREST AS A PHYTOTOXIC AGENT, OR A VERY SHORT NOTE TO THE EFFECT THAT THE COMPOUND IS NOT CONSIDERED PHYTOTOXIC.

3.2.1 IF THE COMPOUND IS CONSIDERED PHYTOTOXIC THE FORM OF THE RECOMMENDED AMBIENT AIR STANDARD CAN BE OF THE USUAL UG/M3 TIME VARIETY OR A DEPOSITION STANDARD OF THE FORM G/M2 TIME OR KG/HA TIME, OR PPM BY WEIGHT/TIME AS IN THE FLUORIDE CONTENT OF FORAGE CRITERION.

3.3 SOILING, CORROSION EFFECTS

3.3.1. THE BEST WAY TO DESCRIBE THE STANDARD SETTING PROCEDURE WHERE THE LIMITING EFFECT IS SOILING OR CORROSION IS TO STUDY THE PROCESS USED IN REVIEWING THE AMBIENT AIR STANDARD FOR CARBON BLACK. A NUMBER OF QUESTIONS WERE RAISED ABOUT THE APPROPRIATENESS OF THIS STANDARD. A SEARCH FOR THE ORIGINAL RATIONALE

SHOWED THAT THERE WAS VIRTUALLY NO BASIS FOR THE 25 UG/M3 VALUE USED FOR THE 0.5H POI ALTHOUGH IT WAS ALSO OBVIOUS THAT THERE HAD BEEN NO SERIOUS OR FOR THAT MATTER ANY FORMAL CHALLENGES OF THE STANDARD. THIS GENERALLY MEANS THAT KNOWLEDGEABLE INDUSTRY ENGINEERS DID NOT EXPECT TO WIN A COURT CASE OR TO CONVINCE A HEARING BOARD THAT THE STANDARD WAS TOO STRINGENT OR ON THE OTHER SIDE, PEOPLE SUBJECTED TO CARBON BLACK POLLUTION DID NOT EXPECT TO TO ABLE TO PROVE THAT THE STANDARD WAS NOT STRINGENT ENOUGH. AT ANY RATE THE ARB LET A CONTRACT THROUGH THE RFP PROCESS FOR AN EXPERIMENTAL INVESTIGATION OF THE STANDARD. THE OUTCOME OF THIS INVESTIGATION WAS A RECOMMENDATION IN THE FORM OF A LENGTHY REPORT BY THE INVESTIGATOR FOR A 24H AAQC OF 10 UG/M3 FOR CARBON BLACK AND THE CONFIRMING OF THE APPROPRIATENESS FOR THE TIME BEING OF THE 25 UG/M3 0.5H POI.

3.3.2 IN THE CASE OF CORROSION, THE SITUATION IS SIMILAR TO CARBON BLACK, THE EXISTING RATIONALE DOCUMENTS ARE WEAK, AND THE ARB'S PLAN IS TO HAVE THESE INVESTIGATED THROUGH THE RFP/CONTRACT PROCESS AS SOON AS FUNDS AND MANPOWER BECOME AVAILABLE. THE OBJECTIVE IS TO DEVELOP A RELATIONSHIP BETWEEN AMBIENT CONCENTRATIONS OF ACIDS AND ALKALIS AND THE CORROSION RATES OF THE COMMON MATERIALS USED. THIS RELATIONSHIP WILL NOT BE EASY TO ESTABLISH BECAUSE THE COMMON AMBIENT LEVELS ARE MUCH LOWER THAN THOSE IN INDUSTRIAL ATMOSPHERES FOR WHICH CORROSION DATA IS AVAILABLE. THE INVESTIGATOR WILL HAVE TO DEDUCE A RATIONALE FOR THE STANDARD.

3.4 ODOURS

3.4.1 HERE THE ARB HAS DONE SOME PIONEERING WORK IN PROMOTING THE USE OF THE ODOUR IMPACT MODEL CONCEPT TO GENERATE LEGISLATION. THE ODOUR IMPACT MODEL IS BASICALLY THE FAMILIAR S SHAPED CURVE OF BIOLOGICAL RESPONSE AND THERE IS REASON TO BELIEVE THAT IT WILL BECOME THE BASIS FOR LEGISLATION ON ODOURS IN MANY JURISDICTIONS. I AM AFRAID THAT I HAVE USED UP MY TIME AND WOULD LIKE TO SUGGEST THAT YOU GLANCE THROUGH THE AGENDA OF THE RECENTLY HELD SEMINAR ON ODOURS WHICH CAN GIVE YOU A MUCH BETTER PICTURE OF WHAT IS GOING ON IN THIS FIELD.

3.5 COMPLETION OF THE STANDARD SETTING PROCESS

3.5.1 WHEN ALL THE RELEVANT RATIONALE DOCUMENTS ARE ASSEMBLED A MEETING OF THE ENVIRONMENTAL AIR STANDARDS SETTING COMMITTEE IS CONVENED.

3.5.1.1 FOR THE COMPOSITION AND PROTOCOLS OF THIS COMMITTEE PLEASE SEE THE HANDOUT "TERMS OF REFERENCE FOR THE EASSC".

PRIOR TO THE MEETING THE RATIONALE DOCUMENTS ARE DISTRIBUTED FOR STUDY BY THE COMMITTEE MEMBERS AND DURING THE MEETING THE SCIENTIST RESPONSIBLE FOR THE PREPARATION OF THE DOCUMENT PRESENTS THE DOCUMENT AND PROVIDES WHATEVER ARGUMENTS ARE NEEDED IN DEFENSE OF THE NUMERICAL VALUE FOR THE 24H AAQC HE/SHE HAS RECOMMENDED. THIS VALUE SHOULD BE ALLOWABLE FOR A LIFETIME OF EXPOSURE BY THE COLLECTIVE EXPOSED GENERAL POPULATION WHICH BY DEFINITION INCLUDES SENSITIVE INDIVIDUALS. SOMETIMES THE RECOMMENDED VALUE IS FOR A SHORTER PERIOD OF TIME SUCH AS 1 H IN THE CASE OF IRRITANTS.

3.5 AFTER THE RATIONALE DOCUMENT IS DISCUSSED THE EASSC MAKES A

DECISION TO ACCEPT, REJECT OR RETURN THE DOCUMENT FOR FURTHER STUDY, ETC.

3.5.1 IF THE DOCUMENT IS ACCEPTED THE CONTAMINANT IS ADDED TO THE LIST OF STANDARDS, GUIDELINES, ETC., AND DISSEMINATED WITHIN THE MINISTRY. THE RATIONALE DOCUMENTS ARE PUBLIC PROPERTY, THIS WAS SO EVEN BEFORE THE PROMULGATION OF THE FREEDOM OF INFORMATION ACT (FOI).

AS TO THE PRODUCTIVITY OF THE EASSC, PLEASE LOOK AT THE BRIEF SUMMARY OF STANDARDS SET SHOWN ON THE OVERHEAD. (A MAXIMUM OF ABOUT 50 CAN BE SET IN A YEAR.) INCIDENTALLY THE NUMBER OF STANDARDS TO BE SET OR REVIEWED IN 89 WILL BE MUCH HIGHER IN VIEW OF THE LARGE NUMBER OF ODOUR IMPACT MODELS OBTAINED FROM THE ONTARIO RESEARCH FOUNDATION.

3.6 AN ADDITIONAL POINT TO RAISE AT THIS STAGE IS THE STATUS OF THE NUMBERS SET BY THE EASSC. THE NUMBERS CANNOT REALLY BE CALLED STANDARDS AS THE WORD STANDARD CARRIES A LEGAL CONNOTATION IMPLYING LEGISLATIVE APPROVAL. THE NUMBERS SET BY THE EASSC ARE THEREFORE CALLED PROVISIONAL GUIDELINES, GUIDELINES OR TENTATIVE DESIGN STANDARDS, THE DIFFERENCE BETWEEN THESE TERMS BEING THAT THEY ARE SET IN ASCENDING ORDER OF CONFIDENCE IN THE DATA USED TO DEVELOPE THE RATIONALES. IT IS EXPECTED THAT THE LEGISLATURE WILL MAKE PROVISIONS FOR IMPLEMENTING THESE AS STANDARDS IN DUE COURSE. AT THIS POINT THE PRESENTATION IS COMPLETE EXCEPT FOR A DISCUSSION OF THE ROLE OF RISK ASSESSMENT. IT CAN BE SAID THAT SOME RATIONALE DOCUMENTS CONTAIN REFERENCES TO RISK ASSESSMENT, RISK IDENTFICATION AND RISK MANAGEMENT WHERE THESE WERE AVAILABLE

AND WERE USEFUL TO THE AUTHOR OF THE DOCUMENT.

CURRENT ISSUES & PROBLEMS

1. REVIEW OF THE BENZENE STANDARD - A POLICY DOCUMENT HAS BEEN SUBMITTED TO THE ARB MANAGEMENT FOR SUBMISSION TO THE MANAGMENT COMMITTEE. THIS DOCUMENT IS NOW AT THE ADM (ASSISTANT DEPUTY MINISTER) LEVEL. THIS PROBLEM IS PERHAPS THE MOST COMPLEX AIR QUALITY PROBLEM IN THE HISTORY OF THE ARB.

2. ODOURS - RESOLUTION OF A NUMBER OF QUESTIONS ABOUT THE USE OF THE 76+ ODOUR IMPACT MODELS OBTAINED RECENTLY. FOR MORE INFORMATION ABOUT THESE PLEASE ASK THE ARB FOR A COPY OF THE PROCEEDINGS OF THE "THINK TANK ON ODOURS" HELD DURING JANUARY 89.

3. DEVELOPMENT OF RATIONALE DOCUMENTS FOR ACIDS AND ALKALIS WITH CORROSIVE EFFECTS.

4. RESOLUTION OF THE ISSUE POSED BY RESPIRABLE PARTICULATE MATTER; WHAT SHOULD THE STANDARD BE FOR THE SO CALLED PM-10 FRACTION, I.E. THE FRACTION OF TSP THAT IS BELOW 10 MICRONS IN DIAMETER. THIS PROBLEM HAS AN ECONOMIC SIDE IN THAT THE 100 OR SO HI VOL INSTRUMENTS OPERATED BY THE MOE'S REGIONS WOULD HAVE TO BE EQUIPPED WITH PM-10 HEADS, THE OPERATORS WOULD HAVE TO BE TRAINED AND THE LABORATORY SERVICES BRANCH WOULD HAVE TO ABSORB THE COST OF INCREASED PROCESSING TIME. OTHER ASPECTS OF THIS PROBLEM ARE THE NEED TO MODIFY THE API AND THE REESTABLISHMENT OF PM-10/TSP/COH CORELATIONS, WHICH MAY WELL BE SITE SPECIFIC.

5. IMPLEMENTATION OF PUBLIC PARTICIPATION IN THE DELIBERATIONS OF THE EASSC:

5.1 WORK ON THIS IS PROCEEDING AND THE ARB IS COOPERATING WITH THE COMMUNICATIONS BRANCH OF THE MOE IN THE DEVELOPMENT OF PLANS TO IMPLEMENT PUBLIC PARTICIPATION.

6. RESOLUTION OF THE ISSUE REPRESENTED BY CONTROVERSY ABOUT THE TRUE ODOUR THRESHOLD OF HYDROGEN SULPHIDE GAS.

6.1 THIS STANDARD IS CONSIDERED TOO LAX IN VIEW OF THE FACT THAT A RECENT STUDY BY AN ONTATIO ODOUR PANEL SHOWED THAT H2S IS DETECTABLE AT 5.5 UG/M3.

6.2 AN AD HOC SUBCOMMITTEE OF THE EASSC CHAIRED BY ECONOMIST, DR. J. DONNAN HAS BEEN STUDYING THE PROBLEM OF THE ECONOMIC EFFECTS OF A CHANGE IN THE STANDARD ON KRAFT PULP MILLS IN ONTARIO. THE PROBLEM IS REALLY ONE OF ENGINEERING CONTROLS FOR DIGESTERS WHICH ARE THE SINGLE MOST EXPENSIVE UNITS OF PULP MILLS.

6.3 A FURTHER TASK FOR STANDARD SETTING IS THE NEED TO HARMONIZE THE STANDARD SETTING PROCESS WITH THE ONGOING CAP PROGRAM. EFFECTIVELY THIS MEANS THAT THE RATIONALE DOCUMENTS WILL HAVE TO BE REVIEWED TO ENSURE THAT ALL THE EVALUATION METHODS PROPOSED UNDER CAP HAVE BEEN APPLIED TO THE DEVELOPMENT OF THE STANDARDS.

LEGISLATION, MANDATE, PROCESS

LEGISLATION: EPA/1980/141, O.R 308-SCHEDULE 1,O.R.872/74
SECTION 8 (PAGE 6)

MANDATE: SECTION 8 REQUIRES CERTIFICATES OF APPROVAL (C OF A) MANDATES USE OF POI'S IN SCHEDULE 1 TO GRANT OR DENY C OF A'S. SINCE POI'S IN 308 LIMITED IN NUMBER TO 100, NEW POI'S ARE NEEDED AS NEW CHEMICALS ARE USED BY INDUSTRY

872/74 PROVIDES ONLY 23 AMBIENT AIR QUALITY CRITERIA, MORE ARE NEEDED FROM TIME TO TIME

RECORD OF PROMULGATION OF STANDARDS

1983	1984	1985	1986	1987	1988
7	12	19	23	20	48

LEGISLATION, MANDATE, PROCESS

PROCESS:

1. REQUEST FOR STANDARD COMES USUALLY FROM FIELD, RARELY AS A RESULT OF ARMCHAIR OBSERVATION OF ENVIRONMENT

2. RATIONALE DEVELOPMENT: A RATIONALE DOCUMENT IS PREPARED WHICH MUST CONTAIN A RECOMMENDATION FOR A 24H AAQC, A CONCENTRATION WHICH IS ACCEPTABLE TO THE GENERAL POPULATION FOR A LIFETIME, IF BASED ON HELATH, OR HAS MINIMAL EFFECTS ON VEGETATION, CORROSION, SOILING, ODOUR. THE AUTHORS OF THE RATIONALE DOCUMENT INCORPORATE RELEVANT SCIENCE SUCH AS RISK ASSESSMENT, AS NEEDED AND IF AVAILABLE.

3. RATIONALE DOCUMENT IS REVIEWED AT REGULAR MEETING OF THE EASSC AND ACCEPTED OR RETURNED FOR CLARIFICATION, ETC.

LEGISLATION, MANDATE, PROCESS

4. IF ACCEPTED THE STANDARD IS PLACED ON THE LIST OF STANDARDS AND BECOMES AVAILABLE FOR DISTRIBUTION, THE RATIONALE DOCUMENTS ARE PUBLIC PROPERTY. SINCE THE STANDARDS SET BY THE RASSC ARE NOT LAWS, THEY ARE SUBJECT TO CHALLENGE, I.E. DENIALS OF C OF A'S, DIRECTOR'S ORDERS, MAY BE APPEALED AND THE STANDARD MAY HAVE TO BE DEFENDED AT A PUBLIC HEARING, TO DATE NO SUCH APPEAL HAS BEEN SUCCESSFUL.

5. INVOLVEMENT OF OTHER BRANCHES, MINISTRIES, ETC.

THE MOL IS THE PRINCIPAL SOURCE OF EXPERTISE, OTHER MINISTRIES ARE RARELY INVOLVED, E.G. MINISTRY OF AGRICULTURE EXPERTISE WAS APPLIED IN DEFINING SOME MILK PRODUCTS.

OTHER BRANCHES: HCC, WR, P&P, WMB, ARE REPRESENTED ON RASSC

PROBLEMS, ISSUES

BENZENE: STANDARD IS OBSOLETE A NEW STANDARD IS NEEDED – A POLICY DOCUMENT IS NOW BEFORE THE MAGMT COMMITTE

ODOURS: MANY EXISTING STANDARDS BASED ON INCOMPLETE ODOUR LITERATURE, NEW ODOUR IMPACT MODELS ESTABLISHED THROUGH RESEARCH CONTRACT WITH ORTECH (ONTARIO RESEARCH FOUND'N) 76 SUCH NEW ODOUR IMPACT MODELS HAVE BEEN DEVELOPED – THESE MUST BE INCORPORATED AS NEW STANDARDS OR REPLACE OLDER STANDARDS WITH WHICH THE NEW ONES ARE IN CONFLICT I.E. LOWER OR HIGHER.

CORROSION: STANDARDS BASED ON CORROSION ARE NOT WELL DOCUMENTED, THE SOLUTION IS TO DEVELOP UP TO DATE NEW SCIENTIFIC RATIONALES BASED ON ACTUAL RESEARCH, THIS IS PLANNED FOR HCL, H_2SO_4, NaOH, CaOH, CaO

THESE EXPERIMENTAL PROJECTS ARE EXPENSIVE AND TROUBLESOME BECAUSE THEY ARE BY NATURE OPEN ENDED, I.E.THE INVESTIGATOR COULD FIND ANYTHING.

TSP

C. DE BARROS

SETTING AQUATIC ENVIRONMENTAL OBJECTIVES AND GUIDELINES

The Aquatic Biology Section of the Water Resources Branch is currently in the final stages of preparing a comprehensive manual of procedures for setting Provincial Water Quality Objectives and Guidelines. This manual, when released, will serve as the written material for the topic "Setting Aquatic Environmental Objectives and Guidelines". The outline of the procedures was presented at the workshops and is included in these proceedings.

PWQO DEFINITION

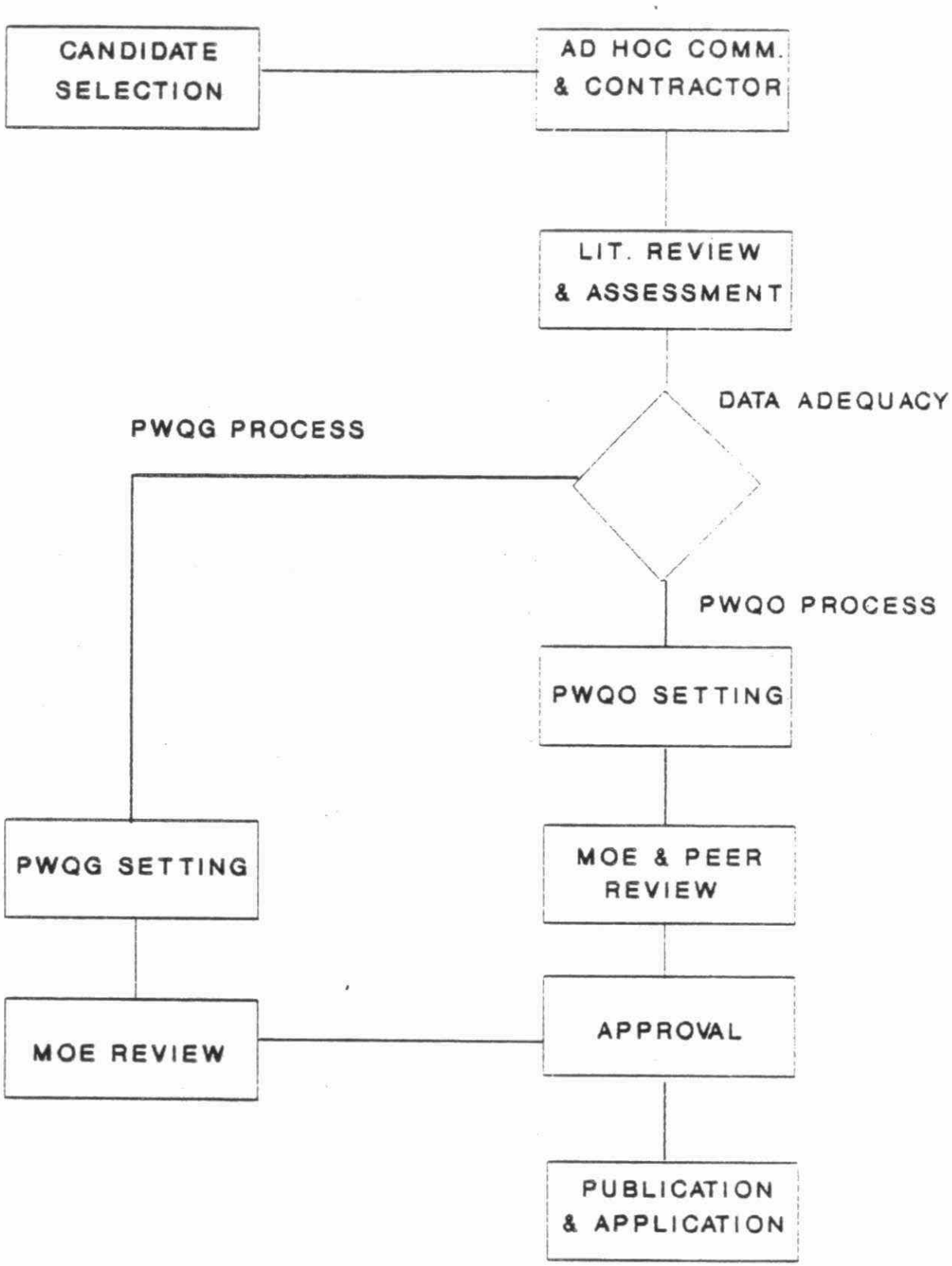
PROVINCIAL WATER QUALITY OBJECTIVES

- numerical or narrative values set to ensure protection of aquatic communities and other uses of surface waters
- established on a sound data base
- used for aquatic impact assessment and/or establishing waste loadings to surface waters

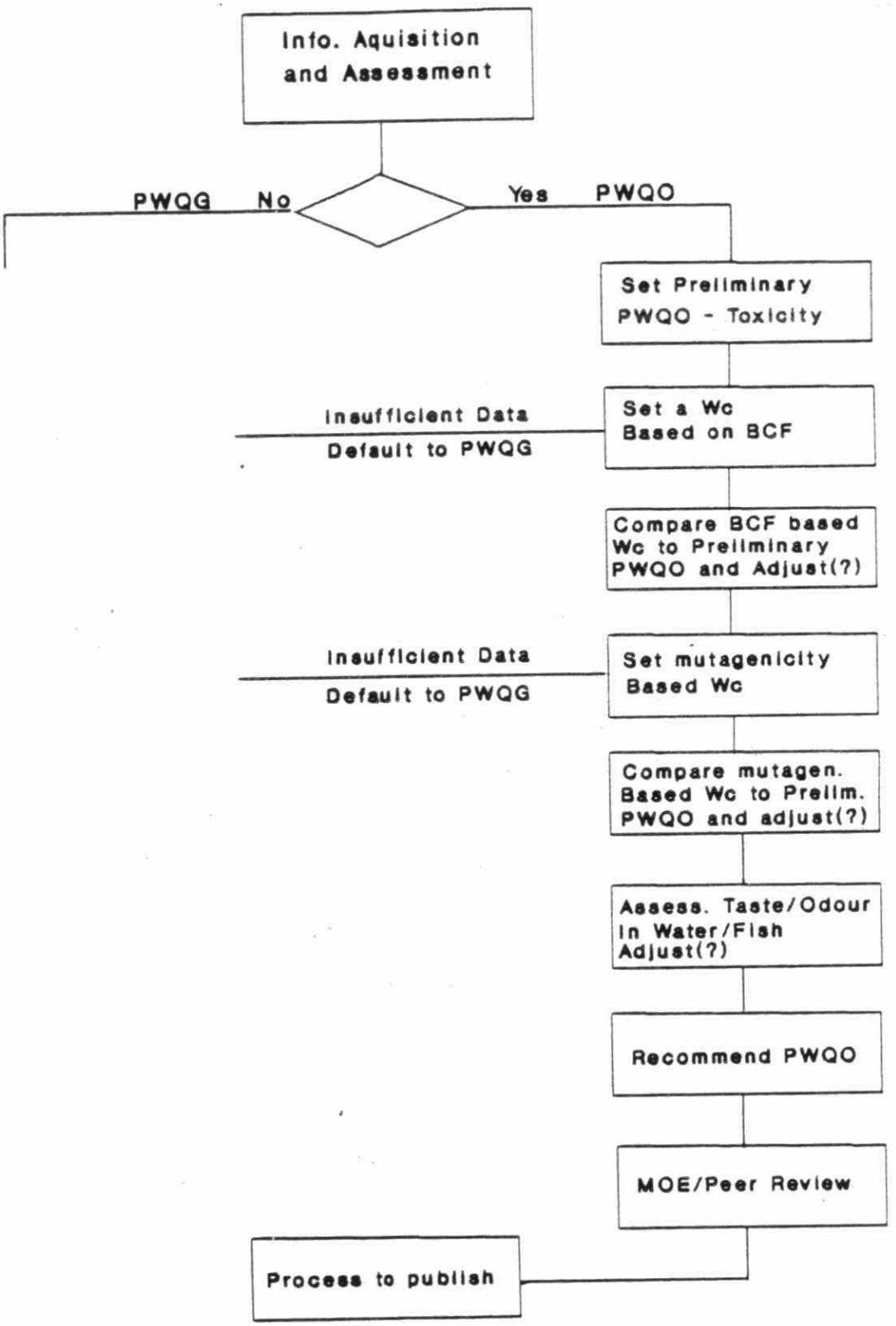
PROVINCIAL WATER QUALITY GUIDELINES (PWQG)

- numerical and narrative values set to ensure protection of aquatic communities and others uses of surface waters
- established when data requirements are not met for development of PWQOs
- uses a sliding scale "safety factor" which is related to quantity and quality of available data
- PWQGs are at least as protective as PWQOs (usually more)

SETTING PWQO/G



PWQO

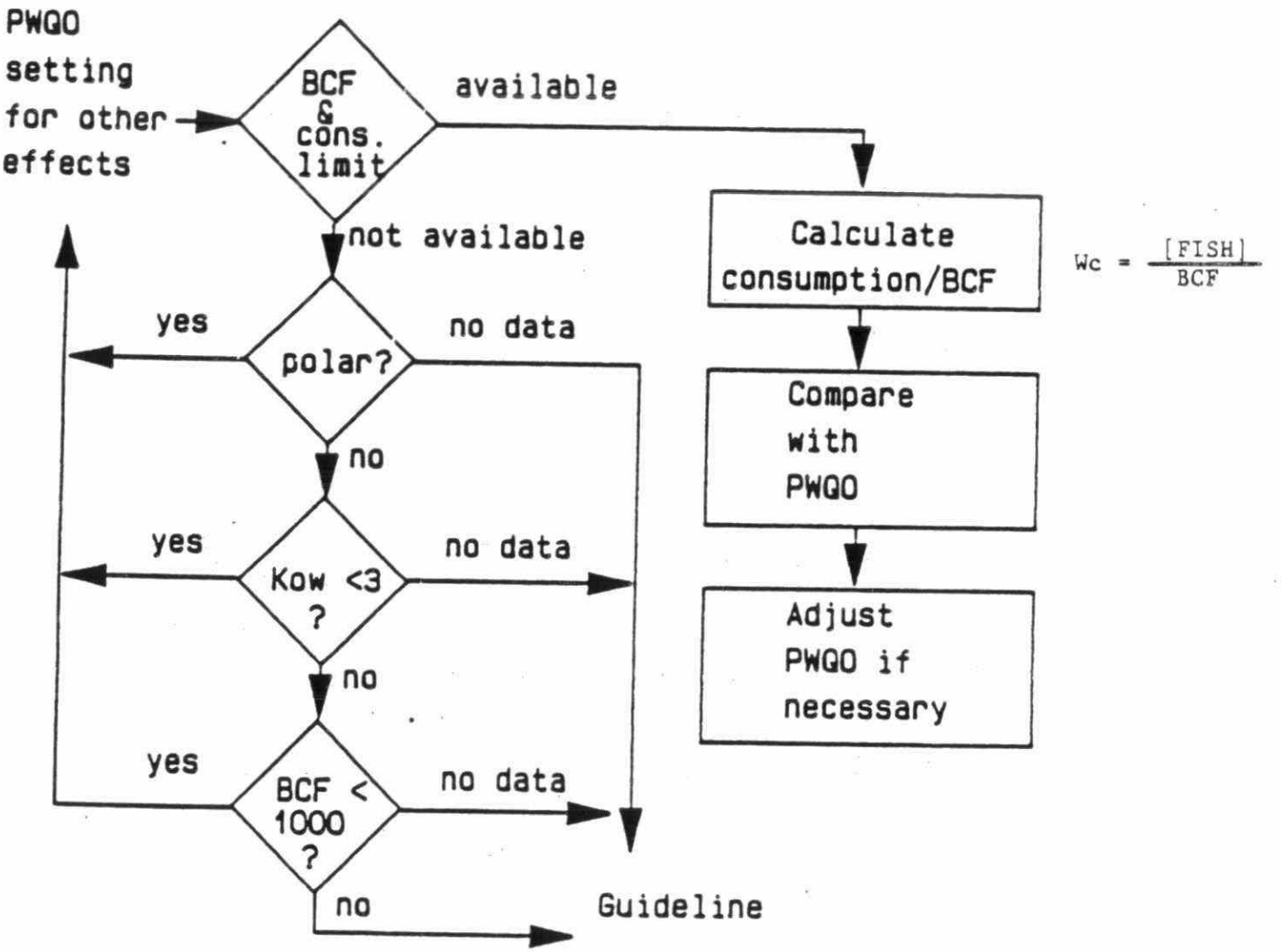

Info. Aquisition and Assessment
PWQG
No
Yes
PWQO
Set Preliminary PWQO - Toxicity
Insufficient Data
Default to PWQG
Set a Wc Based on BCF
Compare BCF based Wc to Preliminary PWQO and Adjust(?)
Insufficient Data
Default to PWQG
Set mutagenicity Based Wc
Compare mutagen. Based Wc to Prelim. PWQO and adjust(?)
Assess. Taste/Odour In Water/Fish Adjust(?)
Recommend PWQO
MOE/Peer Review
Process to publish

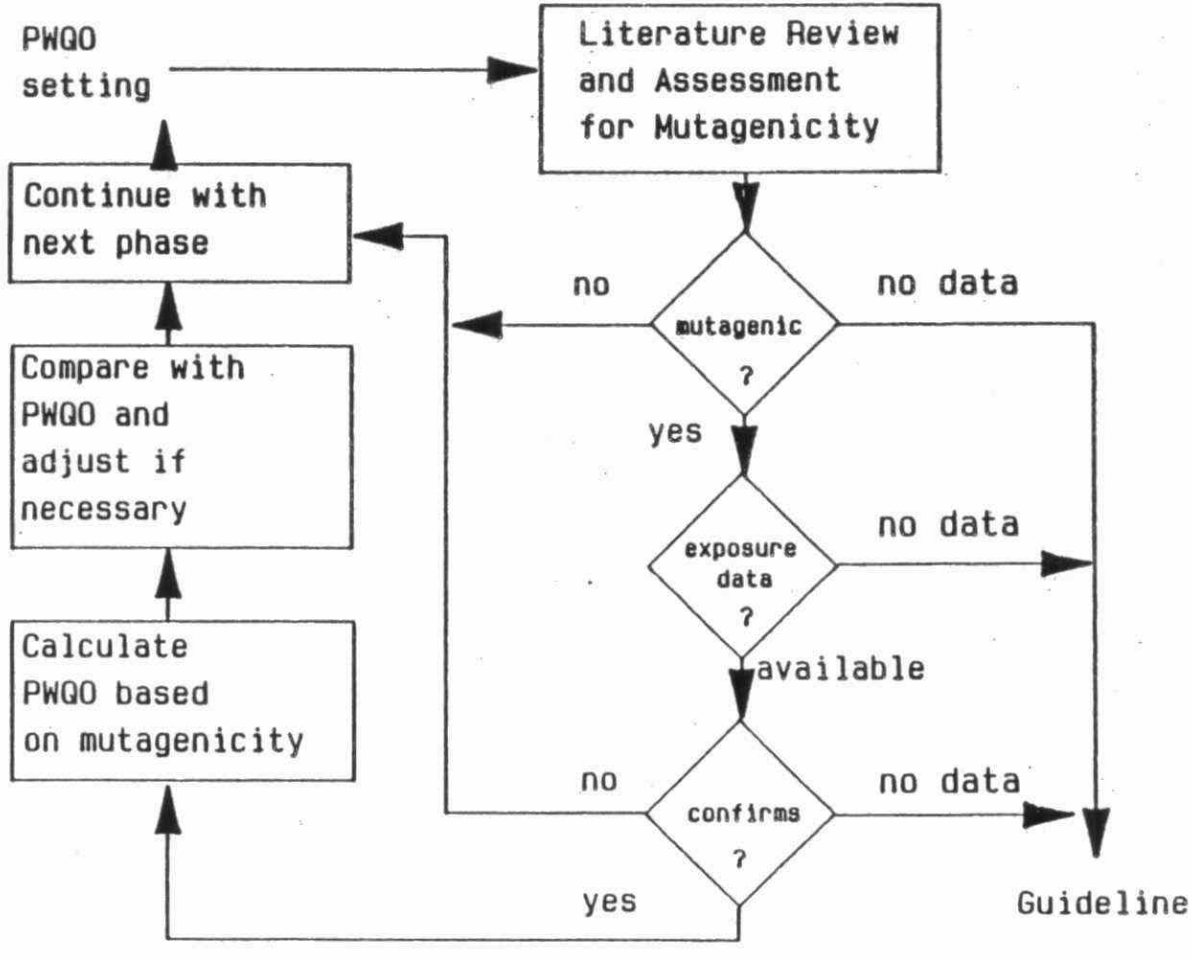
Preliminary PWQO

1. Evaluate aquatic toxicity and report/graph.

2. Identify the lowest chronic endpoint.

3. Set preliminary PWQO at 0.1 times the lowest chronic effect.


PWQO setting for other effects
BCF & cons. limit
available
not available
Calculate consumption/BCF
Wc = [FISH] / BCF
Compare with PWQO
Adjust PWQO if necessary
polar?
yes
no data
no
Kow <3 ?
yes
no data
no
BCF < 1000 ?
yes
no data
no
Guideline


PWQO
setting
Literature Review
and Assessment
for Mutagenicity
Continue with
next phase
no
mutagenic
?
no data
Compare with
PWQO and
adjust if
necessary
yes
exposure
data
?
no data
Calculate
PWQO based
on mutagenicity
available
no
confirms
?
no data
yes
Guideline

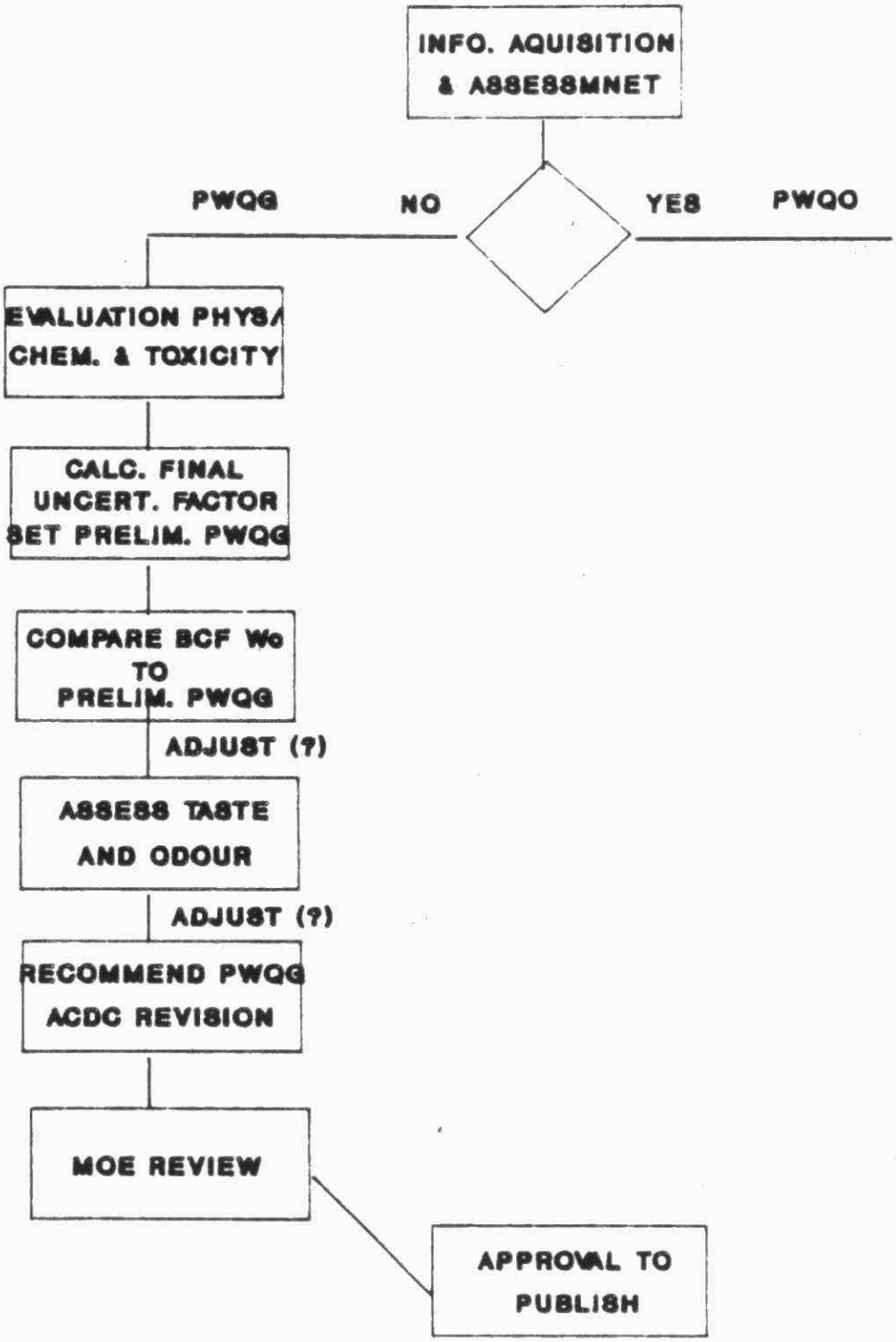
Taste and Odour

PWQOs must not only ensure reproduction, growth and other essential activities of aquatic life are protected but also ensure that the quality of suface waters and fish are protected from taste and odour problems caused by chemical pollutants.

Process

1. Select lowest threshold concentration.
2. Assess the quality of the study.
3. Multiply the lowest threshold concetration by 0.5.
4. Compare the taste/odour concetration to the Prelim. PWQG and adjust (?).

PWQG PROCESS



PWQG PROCESS

STEP #1 BASELINE UNCERT FACTOR

Log Kow < 4 = 1000

Log Kow ≥ 4 = 10,000

STEP #2 REFINING UNCERTAINTY FACTOR

i) Chronic effects data

- 3 fish, 2 invertebrates and 1 plant
- primary vs. secondary

ii) Acute effects data

- 3 fish, 2 invertebrates and 1 plant
- primary vs. secondary

iii) Derived Chronic (A/C Ratio)

iv) Derived Acute (QSAR)

PWQG PROCESS (CONTINUED)

STEP #3 EVALUATION OF BIOACCUMULATION

$$BCF = \frac{[FISH]}{BCF}$$

STEP #4 EVALUATION OF TASTE/ODOUR

– 0.5 X Lowest Threshold Concentration

STEP #5 FINAL ASSSESSMENT

A.VAJDIC

DRINKING WATER OBJECTIVES – AN EXAMPLE OF FEDERAL–PROVINCIAL CO–OPERATION

DRINKING WATER OBJECTIVES

AN EXAMPLE OF FEDERAL - PROVINCIAL CO-OPERATION

INTRODUCTION.

Ontario Drinking water Objectives (ODWO) were first approved by the Ontario Water Resources Commission in 1964. Guideline documents were also published in 1968, 1976 and 1978. The current edition was produced in 1983.

Provinces have jurisdiction over water supplies and the legislative base is provided by the Ontario Water Resources Act (OWR Act) R.S.O. 1980. Section (1) d.

The ODWO are developed as provided for in Section 44 of the OWR Act, indicating that the Minister of the Environment may prescribe standards of quality for potable and other water supplies. The water supplies to which the ODWO apply are those described in Section 23 (9) of the Act, as those supplying more than 5 private residences or at a rate of greater than 50,000 litres per day.

The current objectives are published as Ontario Ministry of the Environment Policy number 15 -06 -01.

Construction of new water works or alterations of existing works may proceed only after a Certificate of Approval is issued by the Ministry of the Environment under Section 23 of the OWR Act. Before issuing such a certificate, the Ministry must be convinced that the proposed works will provide water of acceptable quality ie. that meets the ODWO.

While it is the Province that develops the water quality objectives, it is the Municipalities that are ultimately responsible for ensuring that a water of adequate quality is delivered to the consumer.

Regional staff of the Ministry co-operate with local Health Units and Medical Officers of Health in the application of the Ontario Drinking water Objectives and in controlling potential health problems in community systems. Water supplies which are not governed under the OWR Act are the responsibility of the local health agencies.

GUIDELINE DEVELOPMENT PROCESS

Background. Quality guidelines or objectives are developed for those substances which can cause aesthetic problems in drinking water, as well as for those with potential health-related effects.

Ontario Drinking Water Objectives (ODWO) are developed following a co-operative process between the Federal government, represented by Health and Welfare,Canada and Environment Canada and the Provincial governments.

In 1974 a Federal/Provincial Working Group on Drinking Water was formed under the auspices of the Federal/Provincial Advisory Committee on Environmental and Occupational Health, to develop the Canadian Drinking Water Guidelines. Reporting to the Conference of Deputy Ministers of Health which,through a co-ordinating Committee achieves liaison with the Co-ordinating Committee of Resource and Environmental Ministers (CCREM), this approach was taken to ensure consistency in guideline development on a national scale. The status of the Working Group was raised to that of a permanent Subcommittee on Drinking Water, to reflect the increased importance and public focus on its endeavours, following publication of the 1978 version of the Federal Drinking Water Guidelines document. The Subcommittee is made up of representatives of Health and Welfare, Canada, and representatives from each of the Provinces and Environment Canada. Personnel from Health and Welfare, Canada provide a Secretariat to the Sub-committee.

The Guidelines for Canadian Drinking Water Quality are intended to apply to all drinking water supplies,public and private. However, they are not legally enforceable standards unless promulgated as such by the appropriate provincial,territorial or federal agency. Judicious use of the guidelines results in the provision of drinking water which is both wholesome and protective of the public health.

Ontario usually adopts the Canadian Drinking Water Guidelines as Ontario Drinking Water Objectives, following review of the Guidelines by the Ministry of the Environment On some occasions Ontario has developed its own Objectives on an interim basis, for substances of particular importance/significance for the province eg. for dioxins. Further, Ontario has sometimes set provincial Objectives which have been more stringent than the federal guidelines.

Risk Identification

Substances for which drinking water guideline levels are set, are selected using certain criteria; those most frequently used are:

0 evidence that the substance occurs at significant levels in drinking water

0 documented evidence that the substance can cause acute or chronic illness or aesthetic problems

0 evidence that the substance occurs relatively frequently in drinking water

Some additional considerations are the availability of an analytical method capable of routinely measuring the substance at about 1/10 of the predicted guideline value, and the availability of methods for controlling the substance (treatment techniques) in drinking water supplies.

The provincial representatives on the Sub-committee may suggest candidate substances for guideline setting. In the case of Ontario, the Drinking Water Surveillance Program, which surveys drinking water supplies throughout the Province for more than 150 parameters, has identified

several substances for which guidelines are required based on their occurrence in drinking water. In some cases, where toxicological data are readily available, and there exists a definite potential for the substance to be present in drinking water, the Subcommittee may set drinking water guidelines; this has occurred in the case of a number of pesticides. In still other cases, guidelines may be set in response to public and/or political pressures, whether or not the substance has been found in drinking water.

The guideline setting procedure is time consuming and expensive, and therefore the candidate substances must be subjected to a prioritization procedure by the Subcommittee; substances with existing guidelines, which must be re-assessed on the basis of new toxicological information, must also be included in this prioritization procedure. The prioritization decision depends, for the most part upon the severity of the anticipated health effect, the availability of toxicological information and the frequency at which the substance is found in drinking water. The members of the Subcommittee set the priorities for guideline setting.

Risk Assessment/ Analysis
Guidelines Related to Health effects

Once a substance is selected for guideline development, the first stage in the process is a review of its physical and chemical properties and its health effects. This is usually performed by consultants under contract to Health and Welfare,Canada or one of the provincial agencies on a shared basis. Data from toxicological studies in animals or occasionally epidemiological studies on human populations are collected and summarized. Health and Welfare, Canada experts review and assess the toxicological data and categorize the substance relative to the evidence of carcinogenicity.

The type of risk analysis applied depends upon the category of the substance relative to carcinogenicity.

For non-carcinogenic substances it is believed that there is a dose or threshold below which adverse effects will not occur. For these, an "acceptable daily intake"(ADI) is developed. From lifetime ingestion studies in animals, a " no observable adverse effect level " (NOAEL) is determined. Factors of from 1 to 10 are then applied to account for various elements of uncertainty; these may include :

- the nature of the effect
- variations between and within species
- the potential to interact with other chemicals

Depending upon the quality of the data available, the agreement between studies , the effects of the substance etc., uncertainty or "safety" factors as high as 25000 may be applied.

A percentage of the ADI is then apportioned to drinking water, the remainder being allowed for intake from other sources such as air or food. Usually 20% of the total ADI is allotted to drinking water; however, where

intake from other sources is known to be considerable eg. for pesticides, where the bulk of the intake is attributable to food, the allotment for drinking water is only 1% of the total ADI. The guideline, or maximum acceptable concentration (MAC) is then developed assuming and average daily intake of 1.5 litres of drinking water by a 70 Kg adult.

For substances felt to be carcinogenic, it is generally accepted that no threshold exists ie. that some level of risk is associated with even the lowest exposure.

Two groups of carcinogenic substance are recognized, based on criteria modified from those of the International Agency for Research on Cancer (IARC)(Appendix a).

Group 1 Substances, classified as carcinogenic to man, are those where data from adequate epidemiological studies indicate that there is a causal relationship between the substance and cancer in man (ie. the observed association is unlikely to be due to bias,confounding or chance). Confidence in inferring a causal relationship is increased when the association is strong and observed in several studies, when there is a dose response relationship or when a reduction in exposure is followed by a reduction in the incidence of cancer.

Group 2 Substances, classified as probably carcinogenic in man, possess inadequate data to assess carcinogenicity, either because there are few pertinent investigations or because chance,bias or confounding cannot be excluded as a possible explanation of the results. Sufficient evidence of carcinogenicity exists in animal species (ie. an increase in incidence of malignant tumours in multiple species or strains, in multiple experiments with different routes of exposure and dose levels or the incidence,site or type of tumour or age at onset is unusual). Confidence in the sufficiency of the data from animal studies is increased where there is evidence of a dose response relationship, supporting results from short term tests or evidence of structure-activity relationships.

Risks are estimated using a mathematical extrapolation model, applied to the most appropriate toxicological data, to determine the amount of the substance (the Maximum Acceptable Concentration or MAC) associated with a specific level of risk. The robust linear extrapolation model applied to tumour types considered to be the most appropriate is used and the level of risk commonly used is less than 10^{-5}. Where exposures to the particular contaminant from other sources is significant, the lifetime cancer risk from drinking water should be 10^{-6} or less. There are a number of uncertainties associated with the extrapolation, but the method is based on conservative assumptions and tends to over-estimate rather than under-estimate the risk. The actual risks at low levels, may,therefore, be considerably lower (ie. by one or two orders of magnitude) than the estimated values.

For substances classified as possibly carcinogenic to man(Group 3), the MAC is based upon the ADI method;

however an additional factor of 1 to 10 times is incorporated into the calculation to account for the equivocal evidence of carcinogenicity. In some cases, where there were sufficient data (incidence of benign tumours at several sites in several species) a quantitative estimate of tumour incidence was considered in the derivation of the MAC.

The Ministry of the Environment may request advice from the Ontario Ministry of Labour on the validity of the Health and Welfare toxicological assessments.

It should be realized that there is uncertainty in the scientific database used for the derivation of guidelines. Inadequate study design, poor data on the level,frequency and duration of exposure and differences in sensitivity between species and among individuals in the same species as well as the potential for interaction all contribute to the uncertainty. In addition, extrapolation of responses observed at high doses to those expected at lower doses is a complex process. Thus, in guideline development, the application of sound scientific judgement on a case by case basis is fundamental to the process.

The Federal/Provincial Subcommittee on Drinking Water review the recommendations for acceptable levels from Health and Welfare,Canada, based on the toxicological data and ultimately decide upon a limit based on these recommendations, the level and frequency of occurrence of the substance and socio-economic and other considerations. Further, the MAC's set must be achievable by available treatment methods and measurable by existing analytical techniques. If this is not the case, an "interim MAC" may be established pending the improvement of methods of quantitation and/or treatment.

The development of guidelines is an ongoing process, and new guidelines are set, and existing ones reviewed as new data on exposure and/or toxicological effects become available.

Guidelines Related to Aesthetic Considerations.

The levels of some substances in drinking water must be controlled because of their ability to cause aesthetic problems in the water, or to interfere with good water treatment practices. Consumers may seek other, possibly hazardous sources of drinking water, if the municipal supply is aesthetically unsatisfactory. Water characteristics unique to the province can sometimes lead to Province-specific aesthetic limits which may differ from the Canadian guideline.

An aesthetic guideline is derived upon review of information about the parameter or substance relating to its capability of causing taste and odour, colour or cloudiness in water , or to cause encrustation and excessive soap consumption. For certain parameters eg. the chlorobenzenes , pentachlorophenol, for which aesthetic guidelines are derived, health-related guidelines are also derived. Further where only aesthetic guidelines are

specified, the values are below those considered to constitute a health hazard. The setting of aesthetic guidelines therefore also involves a full review of the toxicological properties of the substance or parameter.

The Ontario Drinking Water Objectives

The Ontario Drinking Water Objectives are published at intervals in booklet form. In addition to the objectives, the booklet contains explanations of the various objectives and their application, as well as a certain amount of background information on the parameters for which objectives have been set. Recommendations on the level of monitoring that should be carried out is also provided. The format of the publication is currently under review, as are the objectives contained in it. The new format will reorganize the material to make it easier for the user to locate specific information.

The booklet is intended for the use of a wide audience, including the public, Medical Officers of Health, public interest groups and consultants; there is a considerable demand for this publication from those individuals in the above groups whose focus is drinking water quality.

PROBLEMS/ISSUES/HURDLES

Data As already mentioned, guideline setting procedures are frequently hampered by lack of adequate databases on exposure and/or toxicology. There is a need to develop and/or upgrade databases and make them compatible across jurisdictions so that reliable exposure data can be obtained, and epidemiological studies can proceed to supplement animal toxicology data.

Process The advantages of a co-operative effort for an endeavour as labour intensive as guideline setting, such as shared costs, shared expertise and elimination of duplication of effort, are fairly obvious. However, the major disadvantage of the current method of setting drinking water guidelines from an Ontario perspective, is the fact that the candidate substance for the procedure must be prioritized ; a high priority for Ontario does not necessarily rate a high priority on a national scale. Therefore substances found in Ontario drinking water may have to wait some time before being given attention in the formal process. Priority must also be given to substances with existing guidelines, when new toxicological information indicates that a revision is necessary.
It should be mentioned that Health and Welfare,Canada personnel are willing to perform "rapid assessments" for particular contaminants of concern on an occasional basis, should an emergency arise. This process does provide an interim limit, which can be used until the final guideline is developed;this was in fact done in the case of several pesticides which were found in drinking water supplies.

Until recently, there was no formal description of the guideline setting process used by Health and Welfare

and the Subcommittee; a draft of the risk assessment method used has now been provided, for review and final approval by the Subcommittee. The part of the protocol which remains of necessity, undefined is that part where "professional judgement" must be used, and where political or socio-economic pressures enter the process.
The criteria used for identifying and prioritizing substances for guideline setting should also be documented.

Criticism has been levelled at guideline setting agencies in general, for deriving different limits for the same substance, even though the same toxicological information is used. This is primarily the result of the necessity for the use of "scientific judgement" in the derivation process (which will differ from expert to expert) as well as because of differing socio-economic considerations which must be applied, and the use of different assumptions regarding water consumption, average adult weights and other factors. It is unlikely that the different agencies will be able to standardize the procedures to eliminate all differences; it is often surprising that the guidelines set by various agencies agree to the extent they do.

As well, the current process relies almost totally on the extrapolation of the results of toxicological testing in animals to health effects in man. Because of the use of conservative models and uncertainty factors, the resultant guidelines may overestimate risks. There is a need for increased effort in the field of epidemiology, to provide supporting information for guideline development.

General There is continued pressure on the Ministry of the Environment to promulgate "standards" for drinking water, rather than guidelines or objectives, which are not legally enforceable other than in special circumstances. However, remedial actions are undertaken when an objective is exceeded in a water supply, and the Ministry is able to proceed with a co-operative approach; objectives provide a more flexible framework than would be allowed in a regulatory environment, and allow the agencies involved to deal with situations on a case-by-case basis while still protecting public health.

SUMMARY

Ontario Drinking Water Objectives are adopted from the Canadian Guidelines for Drinking Water Quality; these latter are a product of a co-operative effort between representatives of the federal and all the provincial governments.

APPENDIX A

Criteria for Classification

Chemicals were classified, by consensus, into four main categories on the basis of the following criteria (modified from those of IARC):

Group I - Carcinogenic to Man

Group I - Data from adequate epidemiological studies indicate that there is a causal relationship between the agent and cancer in man (i.e. the observed association is unlikely to be due to bias, confounding or chance). Confidence in inferring a causal relationship is increased when the association is strong and observed in several studies, when there is a dose-response relationship or when a reduction in exposure is followed by a reduction in the incidence of cancer.

Group II - Probably Carcinogenic to Man

Group II - Data from epidemiological studies are inadequate to assess carcinogenicity either because there are few pertinent investigations or because chance, bias or confounding cannot be excluded as a possible explanation for the results. However, there is sufficient evidence of carcinogenicity in animal species (i.e. there is an increased incidence of malignant tumours in multiple species or strains, in multiple experiments with different routes of exposure and dose levels or the incidence, site or type of tumour or age at onset is unusual). Confidence in the sufficiency of the data from animal studies is increased when there is evidence of a dose-response relationship, supporting results from short-term tests or evidence of structure-activity relationships.

Group III - Possibly Carcinogenic to Man

Group IIIA - Data from epidemiological studies indicate an association between exposure and human cancer but alternative explanations such as chance, bias or confounding cannot be excluded.

Group IIIB - Data from epidemiological studies are inadequate to assess carcinogenicity. There is some evidence of increased tumour incidence in animals but the data are limited because the studies involve a single species, strain or experiment, study design (i.e. dose levels, duration of exposure and follow-up, survival, number of animals) or reporting are inadequate, the neoplasms produced often occur spontaneously and have been difficult to classify as malignant by histological criteria alone (e.g. lung and liver tumours in mice), there is an increase in the incidence of benign tumours only, or it is believed on the basis of information on the mechanism of action that increased tumour incidence is observed only at very high doses.

Group IV - Probably Not Carcinogenic to Man

Group IVA - There is no evidence of carcinogenicity in sufficiently powerful and well-designed epidemiological studies; there is no evidence of carcinogenicity in adequate studies in 2 animal species.

Group IVB - There is no evidence of carcinogenicity in sufficiently powerful and well-designed epidemiological studies; data in animal species are inadequate.

Group IVC - There are no adequate epidemiological data; there is no evidence of carcinogenicity in adequate animal studies in 2 different species.

Group V - Inadequate Data for Evaluation

Group VA - Data from epidemiological and/or animal studies are inadequate (i.e., because of major qualitative or quantitative limitations, the studies cannot be interpreted as showing either the presence or absence of carcinogenicity).

Group VB - There are no data available for evaluation.

A.C.SOCHA

MULTIMEDIA STANDARD SETTING: RISK IDENTIFICATION

is incomplete, as is often the case, the potential for a chemical to partition into various media can be estimated using a model such as the level 1 fugacity-based model (Mackay and Paterson, 1981). This simple model requires a minimal data set: molecular weight, vapour pressure, aqueous solubility and the log of the chemical's octanol:water partition coefficient. Note that for some chemicals, even this basic data set is incomplete. If the model predicts that 5% or greater of the amount released partitions into more than one medium, the chemical is designated as being of multimedia concern.

2.3 Adverse Effects

The next step is to assess the potential of the chemical to cause adverse effects. The chemical is "scored" according to the following parameters: persistence, bioaccumulation, acute lethality, sublethal toxicity, teratogenicity, genotoxicity/mutagenicity and carcinogenicity. Undesirable aesthetic effects such as odour, taste tainting, foaming and turbidity may also be considered. If a chemical scores sufficiently high in one or a number of these aspects, it is considered to be potentially toxic to biota, and is placed on a priority list. A description of the assessment procedure and criteria would be too lengthy for this presentation; for more details, please refer to the EMPPL document (MOE, 1988).

3 Selection of Chemicals for Scientific Criteria Document Development

Once the hazard identification process has been completed, two products will exist: a priority list of chemicals, and a substantial database on the exposure potential and toxic effects of contaminants. The bridge between identification and criteria development is next: the selection of chemicals from the priority list for SCD development.

Several factors may be brought into play in the selection step. A weighted average of the adverse effects scores may be used to internally "prioritize" the priority list; particular chemicals of concern to the public may warrant special consideration; in all instances, expert judgement should be the primary factor. Such judgement can be facilitated by referring to the database created through the identification process. Furthermore, once a chemical is selected for SCD development, the database will be a valuable asset.

Another aspect of "selection" is that of sharing the workload. For example, the federal/provincial Multimedia Guidelines Advisory Committee (which has adopted the MOE screening system) is interested in developing SCDs for multimedia chemicals.

4 Challenges

The most formidable challenge facing us is how to formalize the selection step, i.e. the bridge between hazard identification and SCD development. Up to the present, these processes have not been linked. If the MOE is going to attempt to become more proactive in ensuring the protection of the environment and its dependents, potential problems must be identified before they become immediate concerns.

MULTIMEDIA STANDARD SETTING: RISK IDENTIFICATION

Adam C. Socha
Hazardous Contaminants Coordination Branch
Ontario Ministry of the Environment

1 Introduction

The Hazardous Contaminants Coordination Branch (HCCB) has a mandate to coordinate the development of environmental standards, considering exposure through multiple media. This coordination role is fulfilled in part by the production of *scientific criteria documents* (SCDs). These documents may be described as exhaustive evaluations of literature on toxicology and exposure potential, based on actual exposure, for a specific chemical or group of chemicals. SCDs are used for the purpose of evaluating hazard, providing a basis for setting single-medium standards while recognizing the existence of multiple sources and routes of exposure.

The object of this portion of the presentation is to briefly describe the process used by the HCCB to identify priority chemicals for SCD development. The second portion of the presentation will be conducted by Goff Jenkins, who will cover the process used in developing the SCD itself.

As shown in Figure 1, the hazard identification process includes an initial assessment, or screening, of a relatively large number of chemicals. There are approximately 50,000 chemicals in common commercial use in Canada. Most of the individuals attending this workshop are well acquainted with organic chemistry, and thus it will be appreciated that owing to their innate diversity, many more organic chemicals exist or may be synthesized; however, these are not widely distributed or used except in special applications. Our task is to take these 50,000 or so chemicals and screen them to come up with a priority list of a more manageable (and comprehensible) size, e.g. 300 chemicals. Criteria development will commence on chemicals selected from this priority list.

2 Identification

2.1 Exposure Potential

The first part of the identification process is to look at the "universe" of commercial chemicals and ascertain which of these are likely to be released into the environment in Ontario. Our primary interest is in identifying those chemicals that have been detected in municipal and industrial effluents, in emissions and in the ambient environment in Ontario. Secondarily, we will consider chemicals of concern as identified by recognized regulatory and health advisory bodies (e.g. MOE, Environment Canada, Michigan Department of Natural Resources, U.S. EPA, IARC, IJC) but which have not yet been detected in the environment.

2.2 Environmental Partitioning

Once chemicals have been identified which have at lease the potential for environmental exposure, the next step is to identify those with the potential to exist in multiple media (i.e. air, water, soil and/or sediment). The preferred way to decide this is to look at monitoring data: if a chemical is routinely detected in more than one medium, it is of multimedia concern. A second approach is to look at a chemical's use/release profile: do we know if a chemical goes up a stack, is in an effluent stream, or is dumped into a landfill site? Is its nature of use such that it is released directly into air, water or soil? In the event that the above information is lacking or

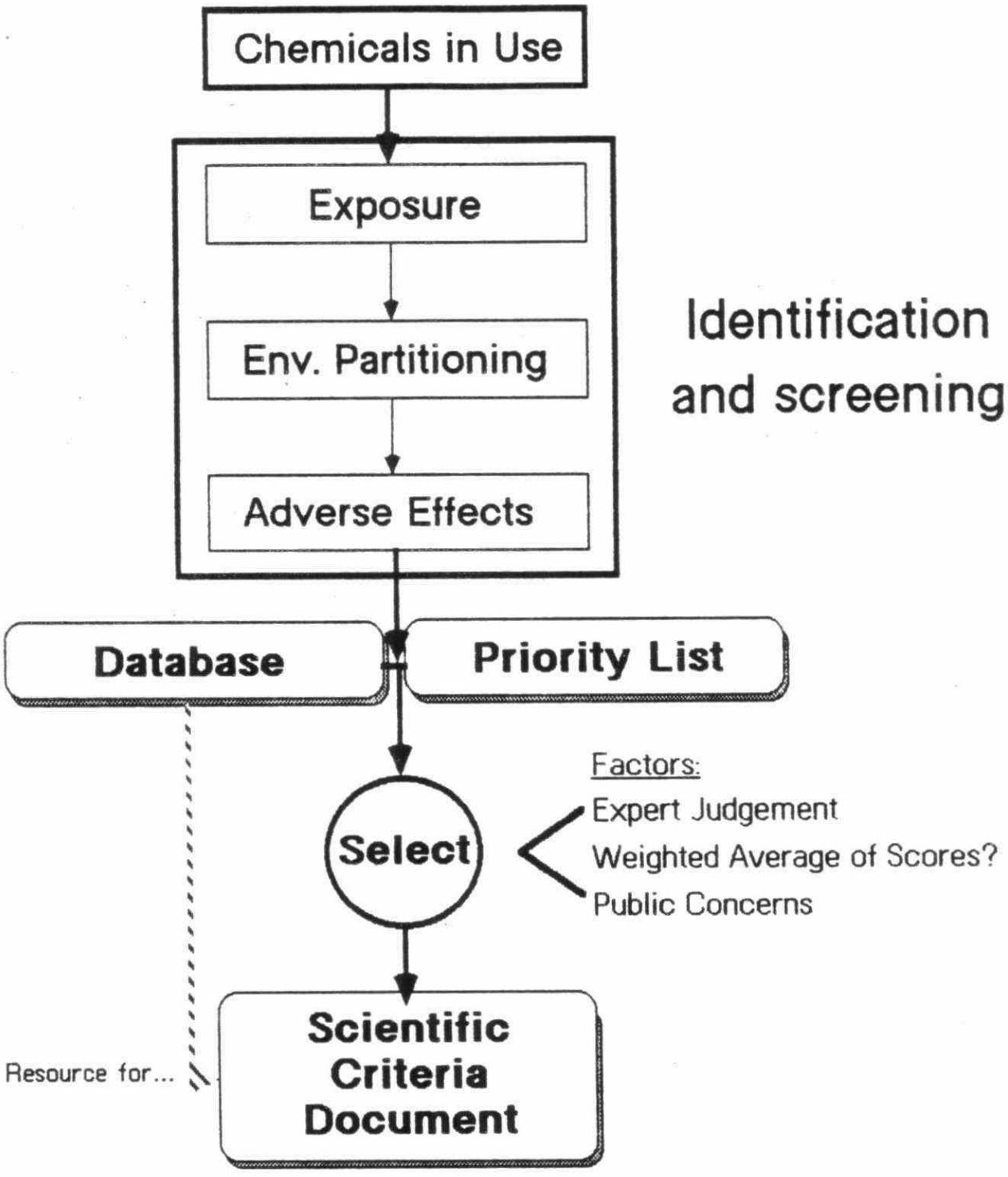


Figure 1

Overview of the Multimedia Hazard Identification Process

G.JENKINS

MULTI—MEDIA STANDARD SETTING: FROM RISK IDENTIFICATION TO THE SCIENTIFIC CRITERIA DOCUMENT

MULTI-MEDIA STANDARD SETTING
FROM RISK IDENTIFICATION TO THE SCIENTIFIC CRITERIA DOCUMENT

G.JENKINS, HAZARDOUS CONTAMINANTS COORDINATION BRANCH
ONTARIO MINISTRY OF THE ENVIRONMENT

1. RISK ANALYSIS - PREPARATION OF SCIENTIFIC CRITERIA DOCUMENT

- THE SCIENTIFIC CRITERIA DOCUMENT CONTAINS AN ANALYSIS OF THE RISKS ASSOCIATED WITH AN ENVIRONMENTAL CONTAMINANT.

- RISK ANALYSIS INVOLVES A PARALLEL ASSESSMENT OF BOTH THE TOXICOLOGICAL AND ENVIRONMENTAL EXPOSURE ASPECTS OF THE CONTAMINANT (SEE FIG. 1).

- THE TOXICOLOGICAL ASSESSMENT IS BASED ON A COMPREHENSIVE REVIEW OF AVAILABLE SCIENTIFIC LITERATURE AND IDENTIFIES DOSE-RELATED TOXIC EFFECTS FOR HUMANS AND FOR THE MOST SENSITIVE RECEPTORS IN EACH ENVIRONMENTAL MEDIUM.

- FIGURE 2 DEPICTS THE MAJOR PATHWAYS AND EXPOSURE ROUTES ASSOCIATED WITH HUMAN EXPOSURE TO ENVIRONMENTAL CONTAMINANTS.

- THE TOXICOLOGICAL ASSESSMENT CULMINATES IN THE DETERMINATION OF A TOLERABLE DAILY INTAKE FOR A CONTAMINANT.

- THE EXPOSURE ASSESSMENT ALLOWS DETERMINATION OF THE TOTAL EXPOSURE TO A CONTAMINANT VIA ALL MAJOR PATHWAYS AND ROUTES OF EXPOSURE, AND IDENTIFIES THE RELATIVE CONTRIBUTION OF EACH SOURCE TO THE TOTAL EXPOSURE.

- COMPARISON OF THE TOLERABLE DAILY INTAKE WITH THE TOTAL CURRENT EXPOSURE PERMITS AN ASSESSMENT OF THE RISK OR HAZARD ASSOCIATED WITH EXPOSURE TO THE CONTAMINANT.

2. DEVELOPMENT OF THE SCIENTIFIC CRITERIA DOCUMENT

- AN INTERNAL EXPERT COMMITTEE, COMPRISED OF REPRESENTATIVES FROM VARIOUS BRANCHES OF THE MOE, OTHER PROVINCIAL MINISTRIES, AND FEDERAL AGENCIES, IS ESTABLISHED TO GUIDE/OVERSEE DEVELOPMENT OF THE DOCUMENT.

3. FROM THE SCIENTIFIC CRITERIA DOCUMENT TO ENVIRONMENTAL STANDARDS

- FIGURE 3 INDICATES HOW THE INFORMATION CONTAINED IN THE SCIENTIFIC CRITERIA DOCUMENT MAY BE USED TO DEVELOP REGULATORY CONTROLS. THIS APPROACH ENSURES THAT TOTAL EXPOSURE TO A CONTAMINANT IS KEPT WITHIN ALLOWABLE, OR ACCEPTABLE, LEVELS.

- IN ADDITION TO THE SCIENTIFIC ASSESSMENT CONTAINED IN THE SCIENTIFIC CRITERIA DOCUMENT, SOCIO-ECONOMIC AND TECHNICAL FACTORS MUST ALSO BE TAKEN INTO CONSIDERATION IN THE DEVELOPMENT OF ENVIRONMENTAL REGULATIONS.

4. SUMMARY

- THE BENEFITS OF THE MULTI-MEDIA APPROACH TO STANDARD SETTING ARE DEPICTED IN FIGURE 4.

- FOR A MORE COMPLETE ILLUSTRATION OF HOW THE PREPARATION OF A SCIENTIFIC CRITERIA DOCUMENT FUNCTIONS IN THE DEVELOPMENT OF ENVIRONMENTAL STANDARDS, SEE THE ATTACHED PAPER BY BIRMINGHAM, ET AL, 1986.

5. REFERENCE

BIRMINGHAM, B., B.H. THORPE AND I. WILE. "DEVELOPMENT OF MULTI-MEDIA ENVIRONMENTAL STANDARDS FOR DIOXINS AND DIBENZOFURANS". IN PROCEEDINGS: 33RD ONTARIO INDUSTRIAL WASTE CONFERENCE, JUNE 15-18, 1986. ONTARIO MINISTRY OF THE ENVIRONMENT, PP. 37-67. 1986

FIGURE 1 - RISK ANALYSIS

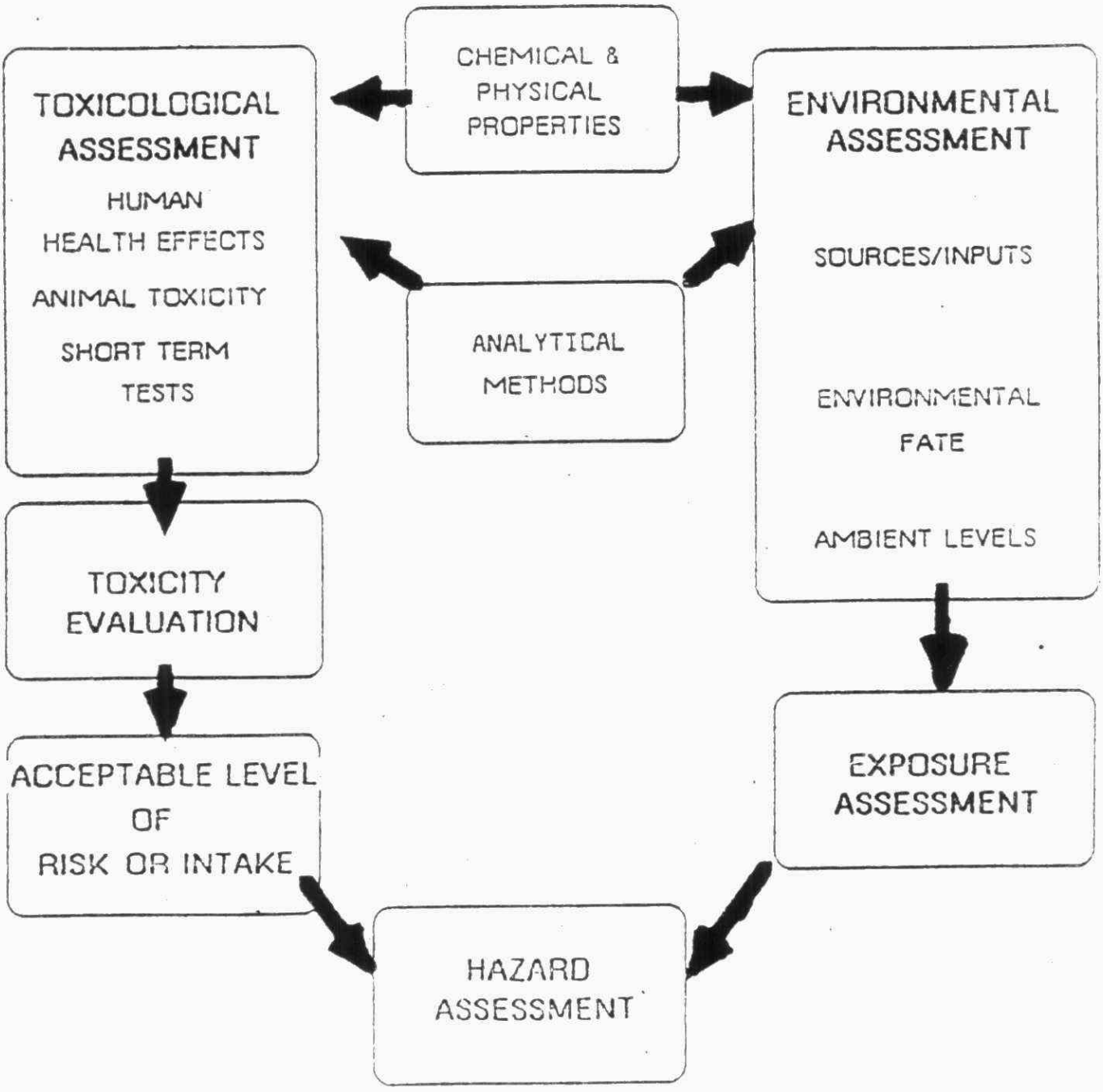


FIGURE 2

HUMAN EXPOSURE TO ENVIRONMENTAL CONTAMINANTS

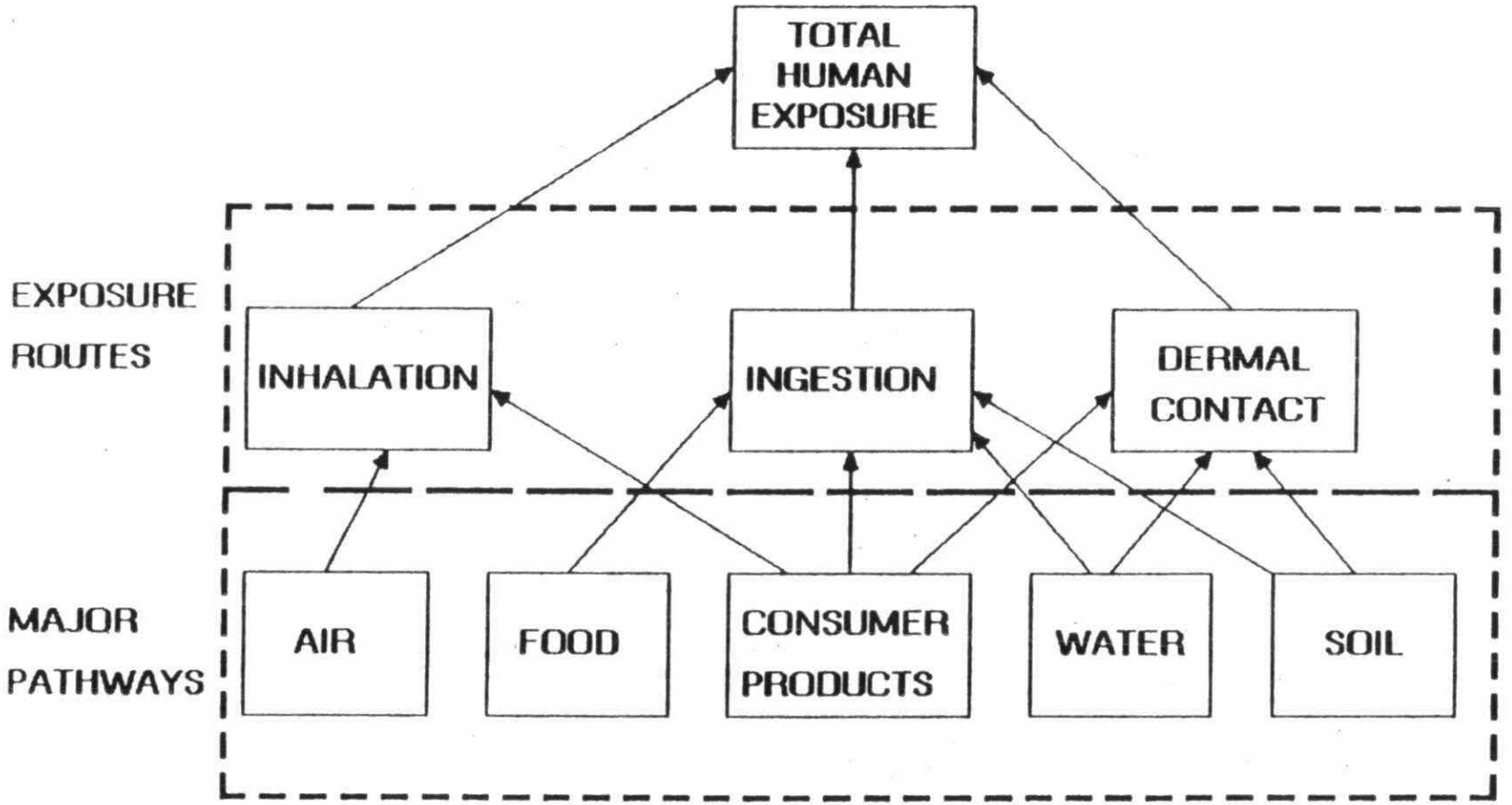


FIGURE 3

DEVELOPING REGULATORY CONTROL LEVELS

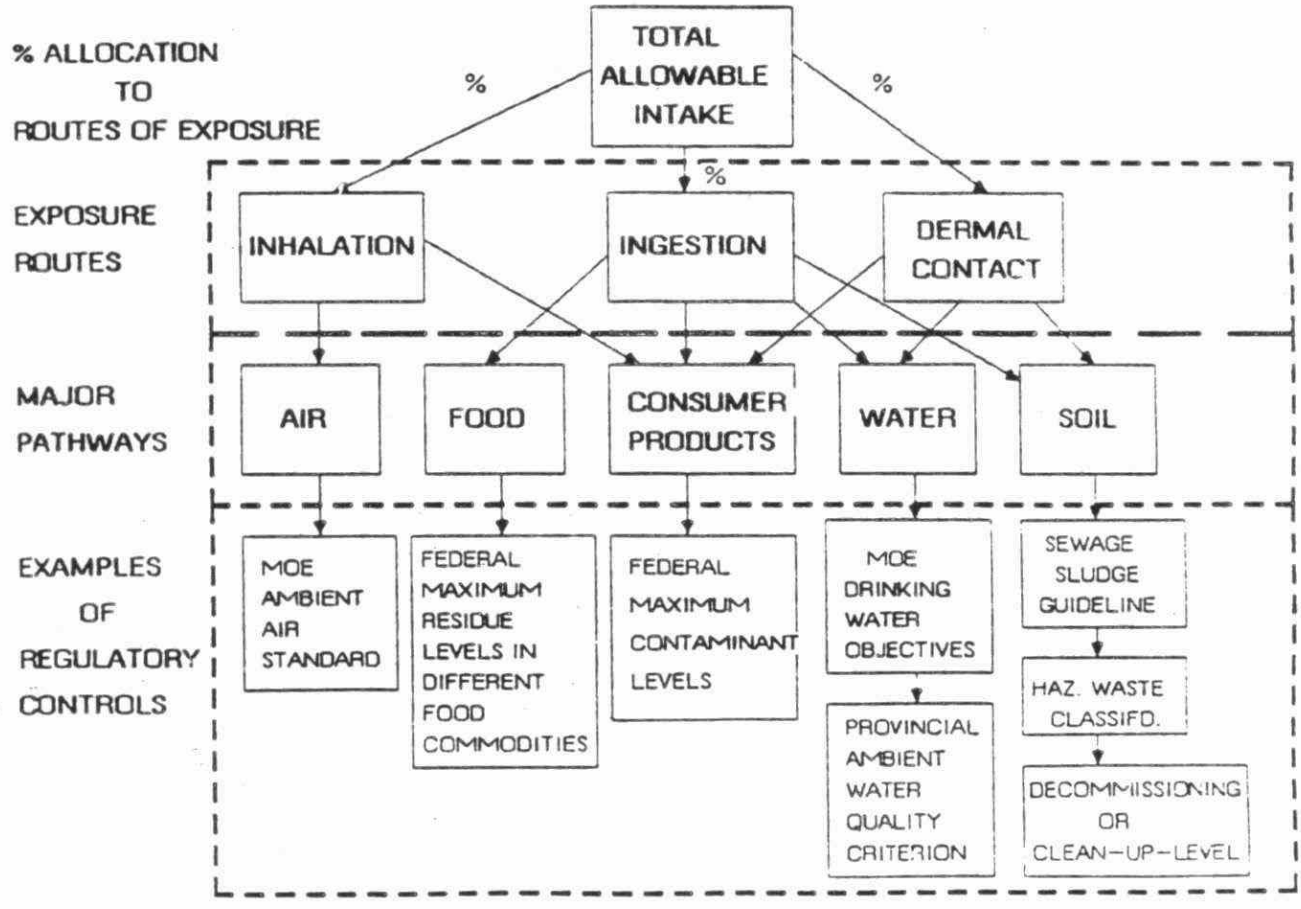


FIGURE 4

BENEFITS OF
MULTI-MEDIA APPROACH
TO
SETTING STANDARDS

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1. ENSURE THAT TOTAL EXPOSURE IS KEPT BELOW MAXIMUM ALLOWABLE INTAKE LEVELS.

2. CONSISTENT RISK EVALUATIONS AND DECISIONS ON ACCEPTABLE RISK ARE MADE FOR THE SAME CONTAMINANT FROM DIFFERENT EXPOSURE PATHWAYS.

3. SINGLE COMPREHENSIVE SCIENTIFIC EVALUATION PROVIDES BEST TECHNICAL ADVICE AND AVOIDS DUPLICATION OF EFFORT.

33RD ONTARIO INDUSTRIAL WASTE CONFERENCE

SESSION 1: CHEMICAL MANAGEMENT

DEVELOPMENT OF MULTI-MEDIA ENVIRONMENTAL STANDARDS FOR DIOXINS AND DIBENZOFURANS.

B. Birmingham, B. Hanna Thorpe and I. Wile, Hazardous Contaminants Coordination Branch, Ontario Ministry of the Environment.

ABSTRACT:

In recent years, there has been an increasing concern over the presence of dioxins and dibenzofurans in the environment. The most toxic form of dioxin, 2,3,7,8-T_4CDD has been found in Lake Ontario fish and in leachates from landfill sites in upper New York state. Both dioxins and dibenzofurans have been found in incinerator emissions, drinking water and most recently in some foods.

In response to these findings, a group of Ministry of Environment and Ministry of Labour experts was assembled in 1983 to prepare a criteria document for PCDDs and PCDFs which would provide the scientific basis for the development of environmental standards for all media. A panel of internationally renowned scientists was appointed to provide technical direction and peer review.

The criteria document which was published in 1985 uses a risk analysis approach with the toxicological assessment conducted in parallel with the assessment of environmental sources, fate and exposure pathways. Since in Ontario, the 75 PCDDs and 135 PCDFs occur as complex mixtures, a system of toxic equivalents was developed based on the toxic potency relationship between 2,3,7,8-T_4CDD and the other dioxins and dibenzofurans.

To protect human health, the document recommends a maximum allowable daily intake for total PCDDs and PCDFs equivalent to 10 picograms 2,3,7,8-T_4CDD per kilogram body weight from all routes of exposure. This number provides the basis for the development of multi-media environmental standards for dioxins and dibenzofurans.

Human beings are exposed to chemicals through three principal routes, namely, inhalation, ingestion and dermal contact. The major pathways which contribute to this exposure are air, food, drinking water and soil. At the present time, a federal-provincial working group is reviewing levels of dioxins and dibenzofurans contributed by these pathways for the purpose of apportioning the allowable daily intake based on their relative contributions to human exposure. This multi-media approach will ensure that the allowable daily intake from all routes of exposure is not exceeded.

INTRODUCTION

This paper is split into two parts - firstly, an overview of the development of the Scientific Criteria Document for Dioxins and Dibenzofurans and secondly, a review of the multi-media standard setting process and how the Scientific Criteria Document is being used.

PART 1 Development of Scientific Criteria Document

Due to our location in Ontario close to the U.S. and sharing the Niagara River, the U.S. media have greatly sensitized us to the dioxin issue through the various events associated with the publicity of the Agent Orange issue, and the Times Beach soil contamination issue, and the Niagara River dump sites.

It now seems that some of the focus on the Niagara situation has been shifted to the St. Clair River system and the Rainy River and our food.

Problem

Because of public concern about the presence of dioxins in incinerator emissions, fish and the threat of leachate from the chemical landfills in Upper New York state, dioxins and furans were identified as a high priority for standard setting.

In 1983, a special branch was formed to coordinate the development of environmental standards using a multi-media approach.

Following are some highlights from the 536 page Scientific Criteria Document produced by this Branch as a part of the standard setting process. Copies of the complete document are available upon request from the authors.

Approach

The approach taken in the development of this particular document, was to initially form an internal expert committee, utilizing expert staff from the Ministry of the Environment (Table 1), with human health expertise obtained from the Ministry of Labour.

The task of this Internal Committee was to review existing guidelines for these substances, to review current literature and our own monitoring data for dioxins and furans in the Province, and to develop the Scientific Criteria Document with human health considerations in mind, since clearly, the receptor of interest was human.

To assist us and to provide scientific direction in the production of this document, the Minister appointed a panel of international scientists to the Ontario Scientific Advisory Committee on Dioxins and Furans (Table 2).

TABLE 1: INTERNAL EXPERT COMMITTEE

Member	Ministries	Expertise
Dr. B. Birmingham (Chairman)	Environment	Environmental Toxicology
Dr. D. Harding	Labour	Human Health
Mr. R. Pearson	Environment	Phytotoxicology
Dr. D. Rokosh	Environment	Mutagenesis
Dr. A. Szakolcai	Environment	Environmental Chemistry
Ms H. Tosine/ Dr. R. Clement	Environment	Analytical chemistry
Mr. D. Wells	Environment	Aquatic Toxicology
Mr. W. Smithies	Environment	Policy
Ms B. Hanna Thorpe (Secretary)	Environment	Environmental Assessment

TABLE 2: ONTARIO SCIENTIFIC ADVISORY COMMITTEE ON DIOXINS AND FURANS

Prof. O. Hutzinger	University of Bayreuth, Germany
Prof. H. Plaa	Universite de Montreal
Prof. S. Safe	Texas A & M University
Dr. E.Y. Spencer (Chairman)	University of Western Ontario
Dr. B. Birmingham (Secretary)	Ministry of the Environment

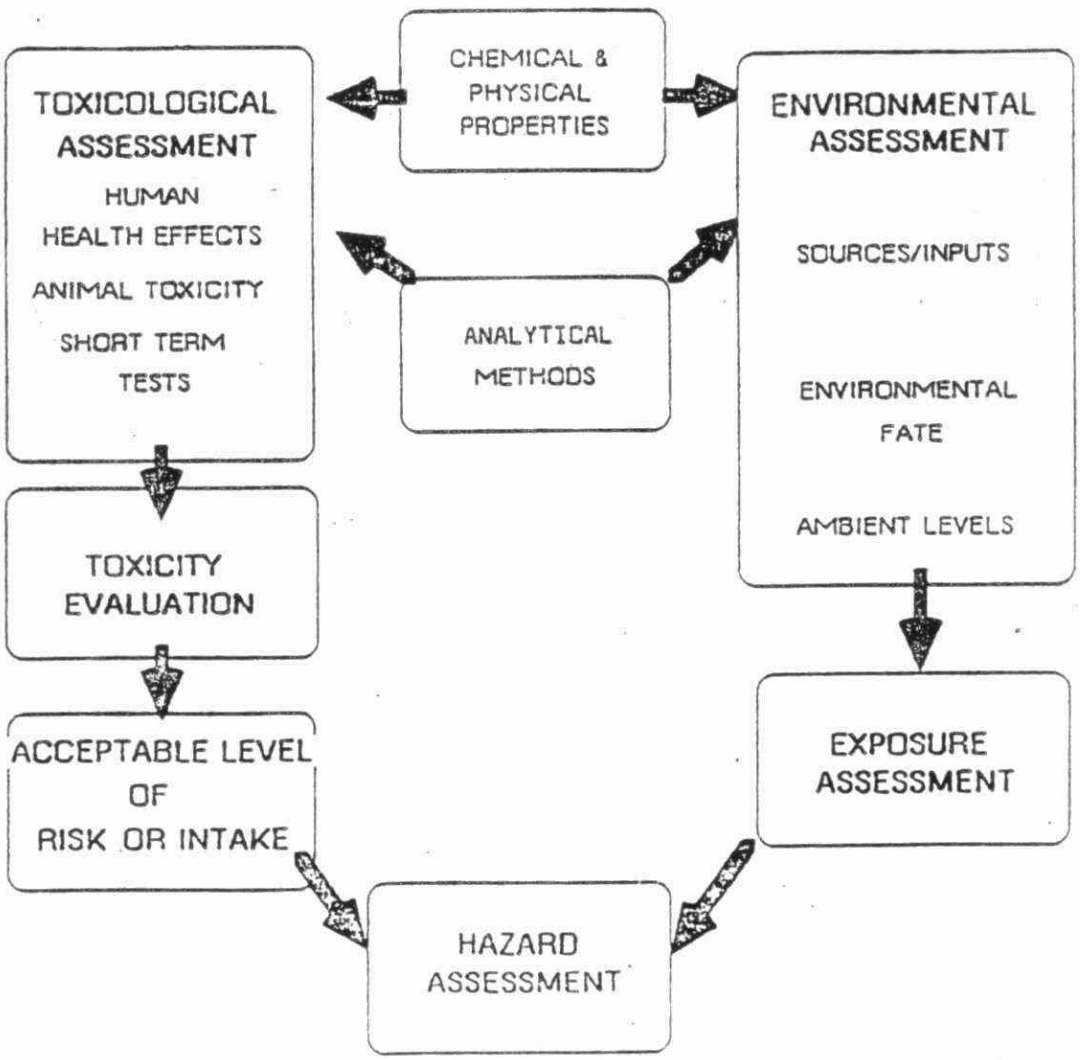
These are international experts, external to our government, whose job it was to ensure a high quality of scientific direction and peer-review of the material produced by the internal committee.

Risk Analysis

We have used what we call the risk analysis approach. This terminology basically defines risk analysis as assessing the toxicological hazard and the exposure hazard separately and then comparing them to come up with an estimate of the toxicological risk (Figure 1). In our approach, the toxicological assessment was conducted in parallel with the environmental assessment.

The basis for the proposed umbrella allowable daily intake was the toxicological data. Basically, we wanted to determine if there was an acceptable level of exposure or acceptable level of risk based on the review of the toxicity data. The exposure assessment is what tells us whether a risk exists or not.

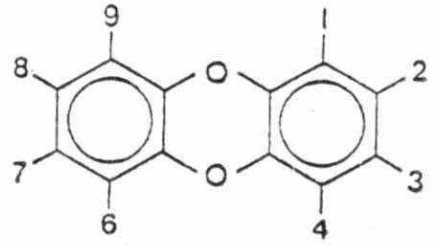
FIGURE 1: RISK ANALYSIS



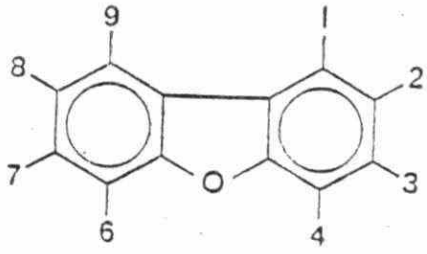
Our aim was to produce an umbrella number for total exposure including diet.

Dioxins and furans have a triple-ring structure, consisting of 2 benzene rings connected to the other via 1 or 2 oxygen atoms (Figure 2).

FIGURE 2:



dibenzo-p-dioxin



dibenzofuran

There are 75 dioxin isomers and 135 furan isomers. The properties of these isomers are related to the number and position of the chlorine atoms attached to the benzene rings.

In most toxic forms of PCDDs and PCDFs are those containing 4-6 chlorine atoms with 4 of the chlorine atoms in the lateral positions, i.e. the 2,3,7 and 8 positions.

At the present time, about a dozen of these 2,3,7,8-substituted isomers, in the tetra-, penta- and hexa-chlorinated isomer groups have been identified as being highly toxic with toxicities only 1/10 to 1/100 that of 2,3,7,8-T_4CDD. These isomers are sometimes referred to as the "dirty dozen".

Toxicological Assessment

As indicated, there are 210 dioxin and furan isomers, however, chronic toxicity data only exists for 3 of them. While we reviewed all toxicity information that we could find on all dioxins and furans, the focus of our review was on the 2,3,7,8-T_4CDD isomer, since this is clearly the isomer with the greatest amount of toxicological data.

In our review of 2,3,7,8-T_4CDD we reviewed all the data on the acute responses such as LD_{50}, enzyme induction, immunotoxicity, short term mutagenicity tests and environmental toxicity tests. We also reviewed chronic responses such as cancer bioassays and reproductive studies in animals. We also looked at the human data and the epidemiological data that was available.

The purpose of our review was to identify reliable, well-validated data; to determine the most sensitive end-point and the most appropriate species if human data was unavailable; and to derive a dose-response relationship from which an appropriate level of protection can be chosen.

TABLE 3: IN VIVO TOXICOLOGICAL EFFECTS OF 2,3,7,8-T_4CDD ON MAMMALIAN SPECIES

SPECIES	DOSE	EFFECT
Acute Responses	(ug/kg)	
Hamster	1157 - 5051	LD_{50}
Mouse	114 - 284	LD_{50}
Rabbit	115	LD_{50}
Monkey	50 - 70	LD_{50}
Guinea Pig	0.6 - 2.0	LD_{50}
Rat/Mouse/Rabbit	0.1	NOEL-Reproductive Effects
Rabbit	0.01 - 0.1	LEL-Keratinization
Mouse	(0.016)	LEL-Immune Suppression
Rat	0.002	LEL-AHH Induction
Chronic Responses	(ug/kg/day)	
Rat	0.007	LEL-Tumour Production
Monkey	0.002	LEL-Reproductive Effects
Mouse	0.0017	LEL-Tumour Production
Rat	0.001	NOEL-Reproductive Effects (3-generation study)
Rat	0.001	NOEL-Tumour Production

As can be seen in Table 3, there is quite a variation in the acute toxicity of 2,3,7,8-T_4CDD. However, at the low end of the range of doses administered, we can see evidence of no observed effect levels. This is also true for chronic responses and gives us an idea of where we should be extrapolating from in order to estimate safe levels of exposure.

A problem that we ran into was related to the fact that 2,3,7,8-T_4CDD is often not detectable in the mixtures analysed in our Province and that there is a very wide range of toxicities amongst the different isomers. Clearly, to assume that all other dioxins and furans in such mixtures are equally toxic to 2,3,7,8-T_4CDD is no longer scientifically justifiable or necessary.

Consequently, we reviewed all the acute and sub-chronic data that we could lay our hands on to construct a matrix of all the known effects of the other dioxins and furans. Also, we took into consideration, the fact that there seems to be a strong structurally-related basis to the activity of these compounds, with substitution in the 2,3,7,8 positions being involved, as mentioned previously.

Since it is clear that it will take decades to accumulate sufficient chronic toxicological data to set a standard for most of the other dioxins and furans that we find in the environment, we

decided to utilize these apparent toxic potency relationships as a basis for proceeding with some sort of interim control strategy for dioxins and furans.

The toxicity ranking scheme that we came up with is shown in Table 4. The factors for dioxins are in the top part of the table followed by the factors for furans. This toxic equivalent ranking scheme involves a number of conservative assumptions. One is that we consider that the effects of all the dioxins and furans in the mixtures are additive.

The other assumption is that the toxic equivalent factor for each group of dioxins and furans is based on the most toxic member of the group. That is the ones with chlorine atoms in the 2,3,7 and 8 positions.

TABLE 4: ESTIMATED RELATIVE TOXICITY OF PCDD AND PCDF ISOMERS TO 2,3,7,8-T_4CDD

ISOMER GROUP	TOXICITY FACTOR RELATIVE TO 2,3,7,8-T_4CDD
DD	Non-Toxic
M_1CDD	0.0001
D_2CDD	0.001
T_3CDD	0.01
T_4CDD*	0.01
P_5CDD	0.1
H_6CCC	0.1
H_7CDD	0.01
O_8CDD	0.0001
DF	Non-Toxic
M_1CDF	0.0001
D_2CDF	0.0001
T_3CDF	0.01
T_4CDF	0.5
P_5CDF	0.5
H_6CDF	0.1
H_7CDF	0.01
O_8CDF	0.0001

* excluding 2,3,7,8-T_4CDD

This gives a very large implicit safety factor since in most cases, the most toxic fraction of each isomer group is usually less than 50% and often only represents 1/10 to 1/100 of the analysed content.

Of course we recognize that as new scientific information becomes available, this interim approach to estimating the toxicity of these substances will, of course, have to be modified.

As can be seen, the factors demonstrate the wide range of toxicities involved.

Rationale for the Proposed
Allowable Daily Intake

The following is a review of the most important points in our toxicological overview of the 2,3,7,8-T_4CDD data which forms the basis of our proposed allowable daily intake summarized in Table 5.

1) The acute toxicity data indicates extreme toxicity with a wide range of sensitivities in different species;
2) The mutagenicity tests are in general negative or inconclusive;
3) A direct mode of action involving direct binding to or direct action on chromosomes or the DNA has not been indicated;
4) 2,3,7,8-T_4CDD is teratogenic and fetotoxic but no effect levels (NOEL) were observed in these tests;

TABLE 5: RATIONALE FOR PCDD AND PCDF STANDARD

TOXICOLOGICAL OVERVIEW (Standard based on 2,3,7,8-T_4CDD)

Acute Toxicity Tests	- extremely toxic (wide range of sensitivity)
Mutagenicity Tests	- negative (inconclusive) - indirect mode of action
Animal Reproduction Tests	- positive (NOEL indicated
Animal Cancer Tests	- positive (NOEL indicated - indirect non-genetic mode of action

Human Health Effects

Short term effect	- chloracne (high exposure
Chronic effects (cancer or reproduction)	- negative (inconclusive)

TOXIC CRITERION FOR STANDARD (Most sensitive effect)

Incidence of liver tumours in female rats
(Kociba et al, 1978)
- well designed, well validated study
- NOEL (0.001 ug 2,3,7,8-T_4CDD/kg body weight/day)

ASSUMPTIONS

- threshold for liver tumours exists (NOEL)
- humans are no more sensitive than rodents
- 100-fold safety factor will provide adequate margin on safety
- toxicity of other PCDDs and PCDFs can be prorated to that of 2,3,7,8-T_4CDD using appropriate factors

RECOMMENDED MAXIMUM ALLOWABLE DAILY INTAKE

10 pg 2,3,7,8-T_4CDD or its equivalent/kg body weight

5) The animal cancer tests with rodents are positive, however, a no observed effect level is also indicated;

6) In terms of the human health effects, the major acute effect is that of chloracne, generally only observed in people who are occupationally or accidentally exposed to relatively high concentrations;

7) Evidence for chronic effects of dioxins on the incidence of cancer or reproductive problems in the human population is negative or at best, inconclusive. Dioxins always occur as contaminants of other chemicals, and currently we are unable to pinpoint effects in the human population that can be specifically nailed down as being caused by only the dioxin or furan component;

8) The toxic criterion for our standard was the study of Kociba et al, 1978. This study is well designed and well validated. The data indicates a no effect level. As far as we are aware, there are no other chronic toxicological effects that occur at lower doses, i.e. that are more sensitive, than these cancer bioassays using rodents.

9) Based on what we know about the activity of dioxins in mutagenic tests, and their general lack of evidence for the direct action on DNA or chromosomes, it was the conclusion of our committees that a threshold for tumours exist in the rodents examined, that humans are no more sensitive

than rodents and that a reasonable doubt exists that 2,3,7,8-T_4CDD will cause cancer in humans at levels below those which have no effect in animals. Consequently, a 100-fold explicit safety factor would provide an adequate margin of safety.

The committee also decided that the toxicity of other dioxins and furans could be pro-rated to that of 2,3,7,8-T_4CDD using appropriate factors.

A basic assumption behind our deliberation was that Ontario citizens are generally exposed to dioxins and furans other than 2,3,7,8-T_4CDD. Therefore, the proposed umbrella maximum allowable daily intake of total PCDDs and PCDFs we have derived is the equivalent of 10 pg (picogram) of 2,3,7,8-T_4CDD/kilogram body weight/day.

It should be pointed out that this number is an annual average and that the daily intake may be lower or higher than 10 pg/kg/day and still be within the guideline. However, averaged over a year the intake should not exceed this daily intake number.

Environmental Assessment

Our estimates of the quantities of dioxins and furans entering the Ontario environment are based on our own monitoring data, and where this

does not exist, we have extrapolated from Canadian or International data sets. One area for which we are currently developing sampling methodologies is ambient air. However, we had to derive estimates of ambient air concentrations based on standard dispersion models.

Table 6 summarizes the findings of the environmental assessment. The sources that we have determined to be of importance are:

1) The use of chemical products contaminated with dioxins and furans. These are principally chlorinated phenols such as pentachlorophenol where the bulk of the dioxins and furans from this source are the less toxic hepta- and octa-chlorinated forms. We have estimated the total dioxin/furan quantity input to the province to be on the order of abut 500 kg per year. There is no 2,3,7,8-T_4CDD in these chemical products now. So that when we apply our toxic equivalent factors, the equivalent toxicity of this quantity of dioxins and furans is quite a bit lower on the order of about 4 kg per year.
2) The second major source is combustion. We have divided this into two major categories; the first category is that of municipal refuse and sewage sludge incineration. These are processes over which we can exert a fair amount of control. The other category is all other combustion processes.

TABLE 6: ENVIRONMENTAL ASSESSMENT (ESTIMATED QUANTITIES OF PCDDS AND PCDFS ENTERING THE ONTARIO ENVIRONMENT)

SOURCE	ESTIMATED CURRENT TOTAL PCDD & PCDF	QUANTITY (KG/YR) 2,3,7,8-T_4CDD TOXIC EQUIVALENTS
1. CHEMICAL PRODUCTS (No 2,3,7,8-T_4CDD now)		
A. Phenoxy herbicides B. Chlorinated Phenols C. Polychlorinated Biphenyls D. Chemical Wastes from A, B and C E. Commercial/ Domestic Products	> 500	> 4
2. COMBUSTION		
A. Municipal Refuse/ Sewage Sludge	29 - 37	8 - 10
B. All other Combustion Sources	100 - 200	20 - 50
3. TRANSBOUNDARY		
A. Airborne	Unknown	Unknown
B. Waterborne	2 - 20	<2 - 20
4. SEWAGE	Unknown	Unknown

We have reasonably accurate estimates of what is produced by the incineration of refuse and sludge, and since a percentage of the isomers in these emissions are 2,3,7,8 substituted, the toxicological quantity of these substances being emitted is comparable with that from all chemical products. Our estimates for the other combustion sources are of necessity, a lot less precise.

Exposure Assessment

Since dioxins and furans are persistent environmental contaminants that have penetrated most media, the assessment of exposure becomes quite complex and by its nature, a multi-media situation. Using ambient level data estimated from the environmental assessment, we modelled exposure via inhalation, ingestion, and dermal contact pathways. Fairly standard models based on the surface area and weight of the body, the volume of air inhaled, the quantity of food and the quantity of water ingested were used.

The conclusions of the exposure assessment which of necessity was a preliminary one, indicated that the major routes of exposure appear to be as follows: The primary one of concern in Ontario is that of ambient air in the vicinity of incineration sources. The next important exposure pathway is that of diet. It is clear that the higher chlorinated isomers such as hepta- and octa-chlorinated dioxins are being found in

some food basket items. 2,3,7,8-T_4CDD has also been found in some sport fish from the Great Lakes and the Rainy River.

The third source that could lead to dioxins and furans coming into the province, is what we call transboundary. This includes long range atmospheric transport of dioxins and furans on air particulate matter, and, waterborne dioxins and furans. We have no estimates of air transport quantities. The principal transboundary source of concern to this Province is through the Niagara River. Federal estimates released about two years ago, suggest that somewhere in the range of 2-20 kg per year of dioxins and furans may be flowing into Lake Ontario via the Niagara River. At this time, it is not clear what the toxic equivalent of this material is.

Another source that we considered was that of sewage. Sewage is the end point of much human and industrial activity, and there is evidence that low levels of dioxins and furans are found in this material. Our reason for being concerned about this material is the very large quantity which is produced by municipalities every year. The recent finding of dioxins in some pulp and paper sludges has accelerated Ministry research into this situation.

The other two pathways of exposure are considerably less important than the inhalation

and dietary pathways of exposure. Soil may be contaminated by deposition of airborne dioxins and furans from incineration activities and our concern was mainly with young children playing in soil who might transfer soil to their mouths during play activity.

The surface water exposure pathway is minor and only applies to people dependent on untreated tapwater near a source of pollution. So far only trace amounts of the octa-chlorinated dioxin have bene detected in treated tapwater at the parts-per-quadrillion detection level. Given the toxic equivalence factor for O_8CDD of 0.0001, this is not a significant source.

Conclusion

An umbrella ADI was developed, based on risk analysis. Using a multi-media approach we have identified major sources and identified problem exposure pathways.

Now having developed an umbrella number, our next step is to partition this into individual standards or guidelines for ambient air, water and waste, in such a manner that these guidelines and standards together, do not exceed the overall intake of the toxic equivalent of 10 pg 2,3,7,8-T_4CDD kg/day.

PART 2 Development of Multi-Media Standards

After completion of the Scientific Criteria Document, the Ministry decided that Environment Canada and Health & Welfare Canada should be involved in developing environmental standards using the scientific criteria document. This decision was made because of:

1) The obvious advantages in having uniform national objectives for these contaminants.
2) The multiple jurisdictions who will be involved in control of dioxins and dibenzofurans from various sources, e.g. Health & Welfare Canada has the primary responsibility for regulating food.

After some discussion, it was decided that the Federal/Provincial Advisory Committee on Environmental and Occupational Health, which has membership from all Provinces and the Federal Government, would be the most appropriate existing mechanism. One of the important standing committees reporting to it, is the group that develops the Canadian Drinking Water objectives.

The Advisory Committee considered Ontario's request and decided to establish an Ad Hoc Committee. This committee is chaired by Health & Welfare Canada, with representatives from Federal and Provincial Agencies.

The Ad Hoc Committee has been given two tasks. The first is to prepare a paper on guiding principles for allocating total allowable intake figures using a multi-media approach considering all exposure routes and pathways.

Secondly, to apply the general approach to dioxins and dibenzofurans using the allowable daily intake figure developed by the Ontario Ministry of the Environment in its scientific criteria document as the starting point. The report of the Ad Hoc committee to the parent advisory committee is expected to be completed in August of 1986.

Subsequently, specific regulatory control numbers can be developed.

Allocation of the Allowable Daily Intake

The allowable daily intake is allocated to the various exposure pathways so that the specific environmental standards can be developed. It is important to emphasize that there is no rigid formula; rather each chemical or family of chemicals should be assessed individually.

Not only the scientific information but also socio-economic and technical considerations become important especially where current levels of exposure from all pathways approaches or exceeds the allowable total intake figure.

Figure 3 illustrates the way that humans are exposed to an environmental contaminant. In Part 1 of this paper, we explained how the exposure assessment was carried out in developing the Scientific Criteria Document for dioxins and dibenzofurans. Of particular importance to the allocation exercise is information on current ambient levels via the pathways leading to the three routes of human exposure.

For example, human beings can ingest a contaminant through air, food, consumer products, drinking water and in the case of children, even from soil.

In Figure 4, which shows the process for the development of regulatory controls, the direction of the arrows has changed from that in Figure 3. In this process, we are going from the umbrella total allowable intake, to allocating a percentage of this intake to each route of exposure and ultimately to the development of appropriate controls shown at the bottom.

In developing the allowable daily intake, you may determine that the toxic end points associated with the major routes of exposure are different.

Once the allowable intake for a specific end point has been set, this value should be allocated only to those routes of exposure which are thought to lead to the specific end point.

HUMAN EXPOSURE TO ENVIRONMENTAL CONTAMINANTS

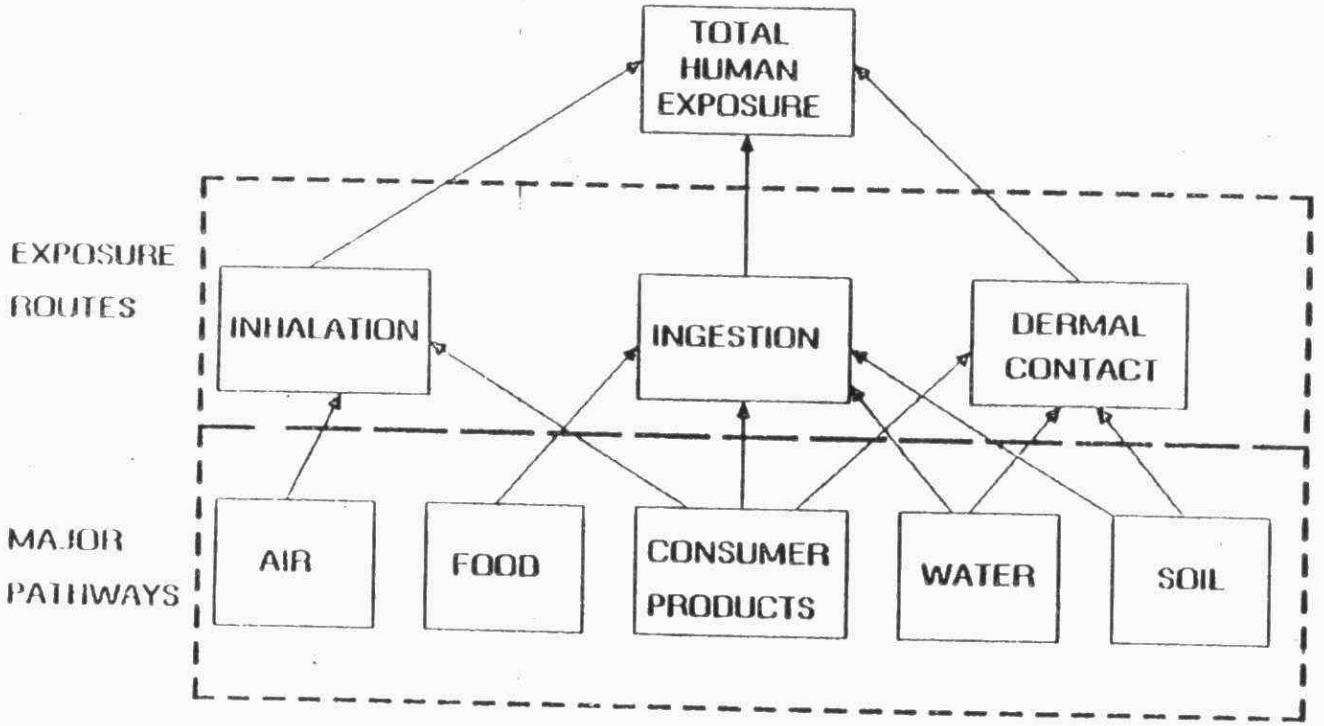


FIGURE 3:

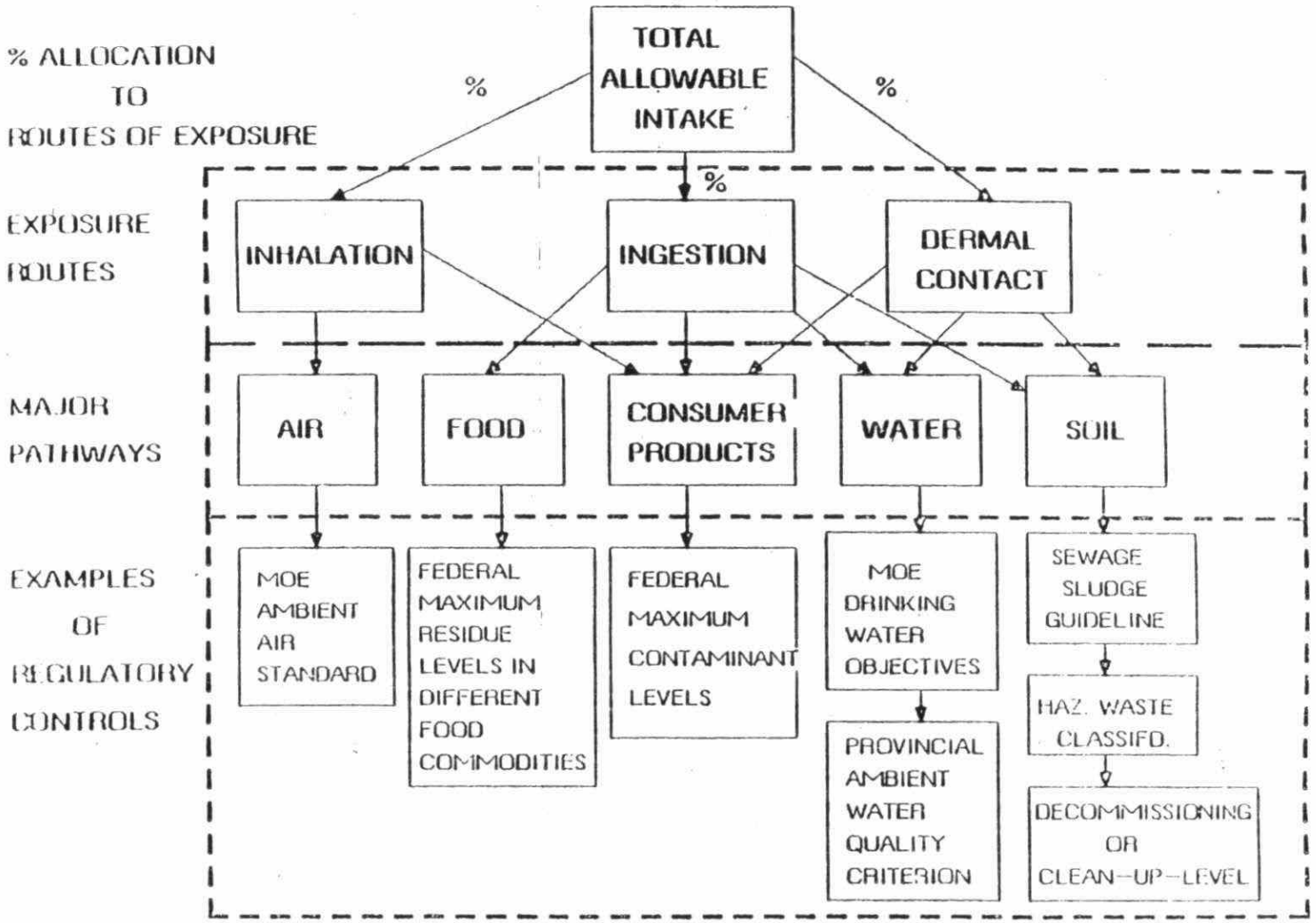


FIGURE 4: DEVELOPING REGULATORY CONTROL LEVELS

In the case of dioxins and dibenzofurans, there is a single allowable intake figure because it is felt that inhalation, ingestion or dermal contact all lead to the same systemic effects.

Allocation to the pathways should be based primarily on relative contributions via each pathway. This will involve both consideration of current exposure levels, based on ambient measurements or estimates, and the proportion absorbed. What this means is that not all of the contaminant which is present in air or food or water is necessarily absorbed by the person who is exposed.

In the case of dioxins and dibenzofurans the Ministry of the Environment has been very active in monitoring for these compounds in a number of environmental pathways,.

The members of the Ad Hoc Committee feel that the data which is available from both Ontario and Federal monitoring, although not complete in every respect, is adequate to allow a recommendation on the allocation of the ADI to the major exposure pathways.

In order to calculate what the maximum allowable ambient concentrations of dioxins and dibenzofurans should be in the various pathways, it is necessary to estimate exposure. This is based on estimating the average amount of air we

breathe, or the amount of different foods we eat, multiplied by the concentration of dioxins and furans found in each of these media. The relative contribution of each pathway then forms the basis for allocation of the ADI and subsequent development of standards and guidelines.

Examples of the kind of regulatory controls that might then be developed are; ambient air standards or in the case of soil, you might develop sludge application guidelines, de-commissioning or clean-up levels, or a hazardous waste classification.

As indicated earlier, decisions on the apportioning of the allowable intake amongst the various exposure pathways may have to consider economic and technical feasibility of control of the various sources.

Where exposure to a contaminant from one pathway is more amenable to control than from another, the apportionment of the allowable intake should take this into consideration. And this is especially true in instances where current overall exposure to a contaminant may approach or exceed the allowable exposure levels. This does not appear to be the case with dioxins and dibenzofurans.

In summary then, the current activity of the Ad Hoc Committee is to recommend how the total allowable intake figure for dioxins and dibenzofurans should be apportioned among the major pathways. It is not part of the mandate of this group to develop the specific regulatory controls.

General Comments on the Multi-Media Approach

Traditionally, guidelines have been developed on a medium-by-medium basis without always giving due consideration to multiple routes of exposure. An important exception to this has been the approach usually used in setting drinking water objectives, where some percentage of an allowable intake is used. But this approach is not generally based on a rigorous scientific evaluation of all routes of exposure.

The single medium approach in many instances is a result of compartmentalized legislation and governmental organization.

In general, human beings are the most important receptor for multi-media contaminants because of their exposure via a number of routes, and because of their place at the top of the food chain.

Standards to protect human health can be based on the effects of either short-term, high-level, or long-term, low-level exposures. Short-term, high-level exposures are not likely to occur simultaneously through multiple media.

Generally, the multi-media approach is applicable to long-term exposures to chemicals which are ubiquitous because they persist, are discharged continually, or have a tendency to bioaccumulate.

Examples of such contaminants are persistent organics such as dioxins and dibenzofurans, and PCBS; persistent metals such as arsenic, cadmium and lead; or ubiquitous contaminants such as polynuclear aromatic hydrocarbons.

The multi-media approach to standard setting is a process by which environmental standards are developed in an integrated manner. Its purpose is to ensure that an acceptable level of exposure from all environmental sources is not exceeded.

This approach to the development of standards provides for more consistent management of chemicals. Such an approach to standard setting may involve multi-agency participation and therefore initially be resource intensive. However, reorganization of regulatory agencies is not necessary. Rather, the approach requires coordination and involvement of a team of

multi-disciplinary experts. Thus it takes longer to develop standards in this way. However it results in consistent decision-making on risk.

The implementation of a strategy to control a contaminant may require the development of specific standards or regulations for controlling the level of a contaminant from various sources. The different agencies which have mandates to develop such standards and guidelines, should do so recognizing a coordinated allocation of allowable exposure levels. In addition, the approach will avoid duplication of effort.

The Ontario Ministry of the Environment is a pioneer in the multi-media approach to developing environmental standards. The Scientific Criteria Document that we have produced for dioxins and dibenzofurans, has been recognized by the Canadian Government and other jurisdictions as a major achievement and break-through. A number of other jurisdictions in the world are also considering the multi-media approach.

For instance, in October, the U.S. EPA is hosting a workshop on behalf of the North Atlantic Treaty Organization Chemical Challenges to Modern Society, on multi-media approaches to the assessment and management of hazardous environmental contaminants. Speakers are being

invited from the U.S., Japan, Germany and Italy and other member countries, to discuss real experiences with various multi-media approaches to share information and to develop new strategies. We have been invited to participate.

In summary, the benefits of the multi-media approach to standard setting include assurance:

1) That total exposure is kept below maximum allowable intake levels.
2) That consistent risk evaluations and decisions on acceptable risk are made for the same contaminant from different exposure pathways.
3) That a single comprehensive scientific evaluation is made which provides the best technical advice and avoids duplication of effort.

Although initially labour intensive, and sometimes difficult to arrange because of organizational obstacles, the product provides the basis for an integrated and comprehensive management of environmental chemicals that treats all sources equitably.

R.R.WEILER

PUBLIC CONSULTATION AND THE ADVISORY COMMITTEE ON ENVIRONMENTAL STANDARDS

PUBLIC CONSULTATION AND THE ADVISORY COMMITTEE ON ENVIROMENTAL STANDARDS

R.R. WEILER
HAZARDOUS CONTAMINANTS COORDINATION BRANCH/MINISTRY OF THE ENVIRONMENT

According to the discussion paper on the Advisory Committee on Environmental Standards (ACES), the Committee will "provide the Minister with recommendations on standards and guidelines for environmental contaminants following consideration of pertinent scientific, legal, economic and social issues and consultation with the public". What is meant by this last term and how can it be carried out?

One definition is given in the policy on public consultation that the Ministry of the Environment is currently preparing. This document defines public consultation as interactive or two-way communication between the public and the Ministry, by which both the public and the Ministry become informed about different viewpoints on issues and proposals. The public can, in addition, influence the Ministry's decision through this proces.

There are two questions that can be posed about public consultation: What are its objectives and what strategies exist for implementing them? The second question will not be dealt with here, except to mention, with some dismay, the point made by Kasperson (1986) that "although a large array of [public] participation techniques exist, current knowledge does not allow for successful prediction as to which are likely to be effective under what conditions."

Keeney and von Winterfeldt (1986) suggest the following objectives that a regulatory agency like the Ministry might want to achieve with public consultation.

1. To educate the public about risk, risk analysis and management, since a better educated public can make more educated decisions and will be more aware of the difficulties, complexities and trade-offs, faced by regulatory agencies in risk management.

2. To inform the public about specific risks and actions taken to reduce them by improving the presentation of risks in terms understandable to the general public.

3. To improve the regulatory agency's understanding of the public's concerns and values. The regulators may be expert on the facts of risks, but there are no "experts" on values.

4. To increase mutual trust and credibility, for without these the public will not accept the information from the agency. To secure trust and credibility, a regulatory must show (Kasperson, 1986):

   - competence in its scientific work;
   - lack of bias in making its decisions; that is, it must not have hidden agendas nor be unduly influenced by special interests;
   - use of due process and of adequate input by the public in arriving at its decisions.

5. To resolve conflicts and controversy. Success depends on early involvement of the public, whose values should be taken seriously and the effort should be one of "joint problem solving". Kasperson (1986) claims that conflicts in public consultation often centre upon "means/ends differences on expectations". The agency sees an instrumental role for public consultation, which is viewed as a means of informing the public of the agency's objectives. The public, on the other hand, tends to approach consultation with an ends goal - who will decide and how will the decision making powers be allocated.

   The public consultation role of the Advisory Committee is specifically mentioned in the proposed public consultation policy of the Ministry. The policy does not, of course, specify how public consultation should be carried out. The fulfilment of the other roles proposed by Keeney and von Winterfeldt (1986) is desirable if the Committee is to fulfil its mandate.

The discussion paper on the Advisory Committee suggests that standards and guidelines should be "consistent with broad social priorities." Their objective can be reached through "consultation with all interested parties." The consultation

process includes distribution of scientific information on the standard, soliciting or written comments, consultation with recognized experts to clarify specific issues and providing feedback to the public, outlining how the public comments were considered. The proposed members of the committee itself, which is to consist of both technical and non-technical members, can be considered as a form of public consultation, since the non-technical members can address the "broad social priorities."

The comments received from the public subsequent to the release of the discussion agreed with the public consultation role proposed for the committee. The main points made are:

- the committee should consist of both technical and non-technical member;

- socio-economic factors should definitely be incorporated into the standard setting process as the public bears the inherent risk and should have a say on what level of risk is tolerable;

- public participation is an integral part of decision making as it broadens the awareness of the public to the many factors that must be considered in standard setting, makes the decisions reached more acceptable to the public and smooths the implementation of the decisions;

- the committee should provide both summary and detailed technical and non-technical information when requesting input;

- the committee should provide feedback to all interested parties. The feedback should include the decisions and recommendations of the committee and the rationale for them as well as any information received during the input stage.

- educating the public about the standard setting process should be one of the major roles of the committee.

The Advisory Committee is in the process of being implemented. Documents summarizing the public input and the role and functions of the committee have been prepared for consideration by the Management Committee of the Ministry. The expectation is that the Committee will be constituted and functioning by mid-summer of 1989.

REFERENCES

Kasperson, R.E. 1986. Six propositions on public participation and their relevance for risk communication. Risk Analysis 6: 275-281.

Keeney, R.L. and D. von Winterfeldt. 1986. Improving risk communication. Risk Analysis 6: 417-424.

DISCUSSION GROUP PRESENTATIONS

TO THE PLENARY SESSION

RISK IDENTIFICATION

A.VAJDIC,A.SOCHA

Risk I.D. Working Group Membership

Leader: Ann Vajdic - WRB
Rapporteur: Adam Socha - HCCB
Facilitator: Gilles Castonguay - WMB

John Miller - HCCB
Jim Richardson - Central Region
Terry Stopps - MOL

Process Used in Discussion

1) Reviewed Workshop objectives and defined "Risk Identification"

2) Reviewed and compared existing methodologies for Risk Identification

3) Categorized methodologies

4) Identified common elements and problems

5) Harmonization - generic approach developed

6) Recommendations

Risk (Hazard) Identification

Definition: Selecting candidate substances for standard* setting

*"Standard" - including guidelines, objectives, criteria

Current Situation

1) Reactive - externally driven

- Certificates of Approval (C of As)
- Situational (case-by-case)
  - decommissionings
  - spills
  - significant levels* detected in medium
  - remediation activities
  - public pressure

* Sometimes internally-generated due to lack of internal communication

2) Proactive - "Flags" potential problems
   - Internally-initiated

- EMPPL approach
  - ° MISA
  - ° PWQOs
- Pre-existing knowledge
  - ° general
  - ° trend monitoring (DWSP, fish monitoring)
- CEPA: assessment of new chemicals
- Registries: ° pesticides
  ° pharmaceuticals
- Literature (alerts; studies in progress, e.g. NTP)

Reactive Approach

Air - C of A's

Waste - Remediation activities

Surface Water - C of A's

Multimedia Standards (Scientific Criteria Documents)

Intermediate Approach

Drinking water objectives

Proactive Approach

Surface Water - MISA
↓
- PWQOs

Why Does The Reactive Approach Predominate?

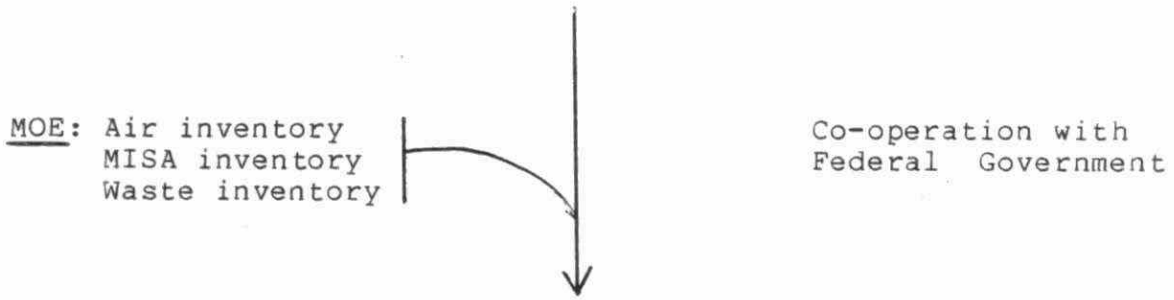
- Overwhelming workload; understaffed
- Little pre-existing information

Possible Solution: Redeployment of resources

Establish a Master List

CEPA Inventory

(Canadian Environmental Protection Act)



MOE Master List
of Chemicals Released into the
Ontario Environment

Prioritization Procedure

Master List

↓

Identify Media of Concern - generates medium-specific lists

- monitoring
- use/release profile
  Release into....
  - water
  - air
  - soil
- environmental transport modelling
  (fugacity)

↓

Prioritize Lists

Generic Prioritization Criteria

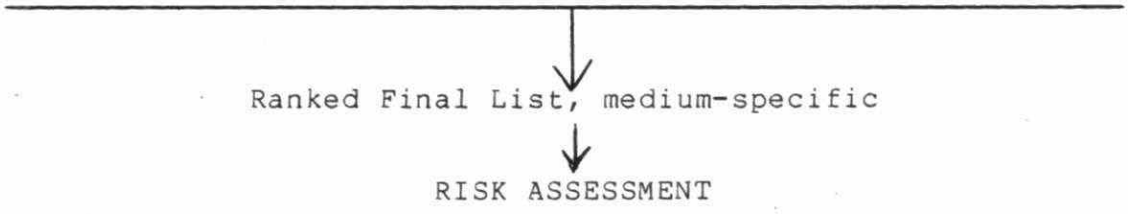
Negative Factors (may lead to subsidiary priority lists)

Lack of.....

- analytical protocol
- toxicology data
- appropriate jurisdictional control (e.g. house dust)
- control technology

Positive Factors

Significant health effects
Significant environmental effects
Level of occurrence (quality) -high
Frequency of occurrence - high
Established routine analytical protocol
Ability to control exists



Recommendations:

1) Develop mechanism for establishing the "MOE Master List"

2) Establish the generic criteria for specific media

3) Customize the generic criteria for specific media

4) Formalize and document the above procedures

5) Emphasize "proactive" approach

    - planning
    - redeployment of resources (to provide sufficient staff, eliminate duplication of effort)

6) Identify data gaps for research needs

    → RAC?

HUMAN RISK ASSESSMENT

A. SZAKOLCAI, B.LEECE

HUMAN RISK ASSESSMENT WORKING GROUP
REPORT TO PLENARY SESSION

Main Components of the Standard Setting Process:

1) Preliminary analysis of data
2) Selection of the standard setting approach, using classification of chemicals and/or their mechanisms of action as a basis
3) Approaches:
   - Allowable Daily Intake (ADI)
   - Dose Response Curves
   - Mathematical Models
4) Presentation of Standard
5) Separation of Standard Setting from other components of Risk Assessment

---

A more complete description of each of these components along with associated issues is included in Appendix A, which was prepared by the working group committee and sent to members of the working group prior to the workshop. A glossary, included in Appendix C, was also prepared by this small committee to clarify terminology for the workshop.

The Standard Setting process, in the context of Human Risk Assessment, has been defined in the glossary as "coming up with a number". Criteria development leading to the "Number", is based upon health effects. In cases where data are readily available, criteria development may include the consideration of exposure via several media through the use of added safety factors.

The working group committee also identified a number of areas of concern within the scope of the working group, some of which are listed in Appendix B. From this list the working group identified and discussed four topic areas which it felt were of the greatest concern:

1) Carcinogen Classification Schemes and their application in the Standard Setting process.
2) Guidelines for the use of Safety (Uncertainty or Protection) Factors.
3) Minimum Information Package to Accompany any Presented Standard.
4) The role of Mathematical Models in Quantitative Risk Assessment.

1. Carcinogen Classification Schemes and their application in the Standard Setting Process

At present, there are a number of schemes for the classification of chemicals as carcinogens proposed by various agencies: U.S. Environmental Protection Agency (EPA), International Agency for Research on Cancer (IARC) and Health and Welfare Canada (H&W). The scheme proposed and used by H&W is outlined below.

Group I	**Carcinogenic:** Compounds which are carcinogenic to humans
Group II	**Probably Carcinogenic**
Group III	**Possibly Carcinogenic**
Group IV	**Probably Not Carcinogenic**
Group V	**Inadequate Data to Classify**

The classification of chemicals in this manner aids in deciding which Standard Setting approach is the most appropriate to use: ADI/Uncertainty Factors or Quantitative Risk Assessment/ Estimation (QRest). For chemicals which fall into Groups I and II, a QRest approach would be most appropriate. For compounds which are classified in Group III, the use of an ADI Approach (with the application of an additional safety factor of 10) may be most appropriate but a QRest approach should also be applied for comparison purposes. For chemicals which fall into Groups IV and V, the ADI approach would be most appropriate.

There was considerable discussion of the stage between the setting of the health criteria, based on toxicology, and the actual setting of the standard. Several factors were mentioned, which should be factored into the standard setting process. For substances falling into Groups I and II, it is desirable that exposure be reduced as much as possible, and that the standard should therefore be set at the lowest level that can be achieved and that can be measured. Information on technological and economic feasibility, and/or analytical detection limits must be considered in standard setting in these cases.

RECOMMENDATIONS:

The working group made the following recommendations:

a) MOE/MOL should review the Carcinogen Classification Schemes proposed by H&W, EPA and IARC, with a view to adopting the most appropriate one to suit its/their needs;

b) MOE/MOL should review the Standard Setting Approaches, including ADI/Uncertainty Factors and Quantitative Risk Assessment which correspond to the various Classification Groups.

c) For QRest especially and for ADI, the setting of a Standard should consist of the following three components:
   i) Lowest Levels (for QRest only). Toxicology Output
   ii) The following factors should also be considered:
      - Technological feasibility
      - Minimum Analytical Detection Limits
      - Existing Levels (Background and Ambient)
   iii) The Standard should be set by considering the output from both i and ii above. It is desirable to keep i and ii separate from each other.

2. Guidelines for the use of Safety Factors

Guidelines need to be established for the use of Safety Factors (two alternative terms for Safety Factors have been suggested: Uncertainty Factor and Protection Factor). The guidelines should outline when it is appropriate to use a given Safety Factor and when its use is inappropriate. Further, the guidelines should provide some direction about the application of the range factors associated with each Safety Factor.

The Safety Factor approach used by H&W Canada is outlined below. The use of this scale assumes that the study being evaluated is adequate.

Range	Factor
10	Intraspecies
10	Interspecies*
1-10	Adequacy of Study
1-10	Nature and Severity of Effect
1-10	LOAEL or NOAEL (NOAEL is preferred)
1-5	Interactions (if known, e.g. Synergism)

*(This may be presented as a range. For example, extrapolating from rhesus monkey to human may have a Safety Factor much less than 10).

Other guidelines for the use of Safety Factors have been proposed by other agencies such as NAS as well as by Dourson and Stara.

One problem associated with the use of Safety factors is that it is a conservative approach which can penalize chemicals for which there is a minimal amount of data.

RECOMMENDATIONS:

The working group made the following recommendations:

a) MOE/MOL should review Health and Welfare Canada Safety Factors.

b) MOE/MOL should adopt/develop guidelines for using Safety Factors, e.g. when should a given factor be used, and how its range value is established.

3. Minimum Information Package to Accompany any Presented Standard

Any Standard which is developed will require the presentation of a minimum information package. The amount and type of information that this package contains will depend upon the type of standard which is being presented.

An ADI based standard will require an information package which outlines the Safety Factors used, the reasons why a specific study was selected for analysis and the basis for the chemical's classification.

A Quantitative Risk Assessment based standard information package should contain various levels of exposure with associated levels of risk, the basis for the chemical's classification, and a summary statement which indicates that the true risk is likely to be much lower than the values reported and may, in fact, be very close to zero (0).

This topic was not exhausted and hence there may be other points/ components which could be part of a minimum information package.

4. The role of Mathematical Models in Quantitative Risk Assessment

There is a need for the development of guidelines for accepting data which can be used in a Quantitative Risk Assessment (QRest) process (i.e., for data to be plugged into the appropriate model).

Some of the currently available models are listed below:

1. Robust Linear Extrapolation (H&W)
2. Linearized Multi-Stage (EPA)
3. Linear Extrapolation
4. Moolgavkar-Knudsen (Biologically based)

RECOMMENDATIONS:

The working group made the following recommendations:

a) QRest is most useful (especially if all estimates are derived using the same model) for:

   i) priority setting among different chemicals

ii) evaluating the risk associated with a technology based standard (i.e. in the process of managing risk reduction)

b) QRest should not be used as an absolute measure of risk (i.e. a standard should not be based solely on achieving an "acceptable" level of risk based on the QRest).

5. Common Databases

An additional point which was raised but not discussed in detail dealt with the need for a national toxicological database that all standard setting agencies would be able to access.

Some currently available databases which loosely fit this description are listed:

1. Michigan DNR (CESARS)
2. CC Info. Future repository of CESARS dossiers prepared jointly by MOE and Michigan DNR
3. IRPTC (WHO)
4. Health Assessment Documents (U.S.EPA)
5. World Health Organization, Environmental Health Criteria Documents
6. VDI

APPENDIX A
RISK ASSESSMENT - HUMAN
WORKING GROUP

STANDARD SETTING IN THE CONTEXT OF RISK ASSESSMENT

Two of the most widely used Risk Assessment/Risk Management models are outlined in figure 1. The NRC/EPA model is used by U.S. EPA and various U.S. states. The model on the right is favoured by Health & Welfare Canada.

Standard setting approximately spans the components in the two models as indicated (see figure 1 and glossary definitions). Magnifying this spanned region, the following components of the standards setting process and associated issues appear to emerge.

1. Preliminary Analysis of Data

2. Selection of Standards Setting Approach. - Using classification of chemicals and/or their mechanisms of action as a basis.

3. Approaches
   - ADI
   - Dose Response Curve
   - Mathematical Models

4. Presentation of Standard

5. Separation of Standard Setting/Risk Estimation from other components of the Risk Assessment/Risk Management process

   General Issue:

   - Does the above cover the essential components of the Standard Setting process?
   - Are any essential points omitted? If so, what?

1 Preliminary Analysis of Data

1.1 Determination of Quality of Available Data

Should MOE use Toxicity Testing Guidelines for judging data quality?
Should MOE use guidelines which are already available? e.g. OECD, EPA.
Are Guidelines needed for special toxicity? e.g. behavioural effects.

2 Selection of Approach

Issues:

2.1 Possible Approaches:

- ADI/Safety Factors Approach - Threshold Effects
- Should the ADI approach be applied to non-threshold carcinogens?
- How could the use of the ADI approach be justified for non-threshold carcinogens?
- Quantitative Risk Assessment Approach - Non-threshold Effects
- Do "Possible Carcinogens" warrant a separate approach? (e.g. larger safety factors)
- Novel Approaches (e.g. Relative potencies, etc.)

2.2 Factors to be Considered in Selecting the Approach:

2.2.1 Classification of Individual Compounds

Points to Consider:

- Should chemicals be classified as human carcinogens, probable human carcinogens, possible human carcinogens, non-classifiable or non-carcinogens on a weight of evidence basis?

- Should closely related approaches (e.g. rank ordered categories of evidence) be used for determining mutagenic and teratogenic hazards to humans?

- Some chemicals have already been classified by other agencies. Do we accept the classifications of agencies whose classification process meets our requirements and standards or, do we spend the time to classify each chemical/mixture in house?

- Can other agencies be added to the list outlined below?
  i) IARC (latest)
  ii) EPA (being revised)
  iii) Others?

2.2.2 Mechanisms of Action

Points to Consider:

- Is it essential to further classify carcinogens as initiators, promoters or complete carcinogens?

- Are there any other subclassifications which we should consider? Completers for example?

- How do we deal with the possibilities of synergistic, additive or antagonistic effects between two individual compounds?

2.3 Problems Specific to Mixtures

Points to Consider:

- Can the components of a mixture be treated as individual compounds whose activities can be summed to derive the overall activity of the mixture?

- Should we consider the carcinogenicity (activity) of the mixture as a whole?

- Toxic Equivalency Approach? e.g. PCDD/PCDF

- Relative Potency Approach? Extrapolation of activity of an environmental test mixture based upon the activity of a given reference mixture.

- Biological monitoring?

- Aggregating Risk?

- Approaches for assessing the risk of chemical mixtures need to be worked out.

3 Approaches to Standard Setting

3.1 ADI Approach

Points to Consider:

- How do we apportion ADI to several media? What short-cut approaches are available?

- ADI is based on NOEL and NOAEL, but how do we define "ADVERSE"?

- Can we make the distinction between irreversible and reversible responses as adverse and not adverse? Some reversible responses if prolonged, do become essentially irreversible.

- How do we intend to deal with sensitive subpopulations?

- Must the distinction between Irreversible and reversible response also account for single and repeated exposure to a chemical which causes a reversible response?

- What is the best name for "Acceptable Dose"?

- How do we determine size of the safety factor

- Is there a need for guidelines regarding priority endpoints?

- Can available severity rating scales be used?

- ADI, Tolerable Dose (TDI/TWI), or Reference Dose? Which of these expressions is the best one to use when expressing a standard?

- What are the important factors in route-to-route extrapolations? (e.g. oral data being used to set inhalation standards).

3.2 Dose Response Approach to Standard Setting

Issues: Use of Dose-Response Curves

Points to Consider:

- How are we to distinguish between Dose-Response curves derived from raw data and those generated by mathematical models?

- There is also a need to distinguish between Dose (absorbed concentration) and Intake (Applied concentration)

- Is the use of Dose-Response Curves with appropriate corrections suitable, or should we focus our efforts on an identified "Most Sensitive Receptor"?

3.3 Mathematical Models

Issues

3.3.1 Justification of Model Choice

Points to Consider:

- Whatever model is used, all assumptions and justifications must be outlined in detail so that it is clear exactly what has been done and why.

- What factors should be considered when choosing a mathematical model?

3.3.2 Adoption of Previously Reported Values

Points to Consider:

- Should we be ready to adopt values (e.g. VSDs or Unit Risks) reported by other reputable agencies or should we develop our own values in-house?

3.3.3 Refining Accuracy of Model Predictions

Points to Consider:

- What adjustments could be made to refine the accuracy of the predictions? e.g. Pharmacokinetic modifications.

- Do all Models warrant refined predictions using pharmacokinetic and pharmacodynamic data? (i.e. will the increase in model accuracy justify the time and effort required to achieve it?)

3.3.4 Single or Multiple Standards

Points to Consider:

- Should a standard be set at a single level or should the results be presented as a range of numbers with their corresponding levels of risk? What are the implications?

- How do we apportion risk to several media? What short-cut approaches are available?

- What terminology do we use, V.S.D., U.C.R., etc.?

4 Presentation of a Standard

Issues

4.1 Possible Ways of Presenting the Standard

Points to Consider:

- Is there a need to present two standards; one derived from the ADI approach and the other from the Mathematical Models? (i.e. especially in cases where the choice of approach is not clear)

- Should final standards (both ADI-based and Risk-based) be presented as two levels. One level for which the risk to the population is acceptable and a second level which would be desirable?

- Should level of risk be determined by the standard setting agency whether it is acceptable or not?

- What is the "Minimum Information Package" that should accompany the presentation of a health based criterion?

5 Separation of Standard Setting/Risk Estimation from other Components of Risk Assessment/Risk Management

Issues: Should the following considerations enter into the setting of Standards?

5.1 Is Standard Achievable?

Points to Consider:

- Is the Standard achievable by available controls or measurable by available analytical methods? If not, should a standard be set or should an interim value be established?

5.2 How does the Standard Compare with Existing Environmental Levels?

Points to Consider:

- Should a Standard be set if existing environmental levels greatly exceed the proposed Standard?

FIGURE 1: US EPA and Health and Welfare Canada Risk Assessment/Risk Management Models

A MODEL FOR RISK ASSESSMENT/RISK MANAGEMENT
(HAP 1983, p. 1990)

APPENDIX B
PARTIAL LIST OF POSSIBLE DISCUSSION ITEMS

- Should the Government use existing guidelines for data quality evaluation or develop their own?

- Do we accept carcinogenicity classifications of other agencies?

- Do we accept the classification of non-cancer endpoints from other agencies?

- Should we accept a scientific criteria upon which a standard is based without accepting the actual standard?

- What is the role of Quantitative Risk Assessment (Mathematical Models) in standard setting?

- Is it possible to standardize the use of safety factors?

- The use of TLVs as a basis for environmental standards.

- Do we choose the "Standard Setting Approach" based on a particular classification, provided no divergent mechanism of action argument is available?

- What is the "Minimum Information Package" required for a risk-based standard to avoid misinterpretation?

- Risk-based Standards:
  One value at one risk level versus several values at several corresponding risk levels.

- What is the appropriate term for the Risk-based standard?
  (VSD, UCR, RMC, Safe concentration)

- What is an appropriate basis for an ADI?
  (NOEL, NOAEL, LOEL, LOAEL)

- What is the appropriate term for ADI-based standard?
  (Criteria, Reference Dose, RMC)

- Mixtures - Approaches closest to applicability in setting standards:
  i) Toxic equivalents
  ii) Relative potency
  iii) Summing Activities of individual components

- Examples of chemical classes and/or complex mixtures where the development of complex mixtures approach would be desirable (e.g. Coke oven emissions, used motor oils, etc).

- What are the preferable options if the standard about to be set is:
  i) not achievable by current controls
  ii) not measurable by available analytical methods
  iii) Greatly above existing environmental levels?

- What are appropriate factors to consider when making route-to-route extrapolations (e.g. oral to inhalation)?

GLOSSARY OF KEY TERMS AND DEFINITIONS

Some of the terms below appear in the two most popular (attached) models for Risk Assessment/Risk Management (RA/RM). Their source will be identified as "U.S. EPA" (United States Environmental Protection Agency) or as "H&W" (Health and Welfare Canada).

Preferred definitions for this Standards Setting Workshop are labelled with two asterisks "**" to try to ensure that we are on the same wavelength.

1 Terms Associated with Major Components of Risk Assessment/Risk Management Models

HAZARD IDENTIFICATION (U.S. EPA)

- Determination of whether a particular chemical is or is not causally linked to particular health effects.
- Seeks answer to the question: Does the agent cause the adverse effect?
- First component of U.S. EPA "Risk Assessment" process.

** DOSE RESPONSE ASSESSMENT (U.S. EPA)

- Determination of the relation between the magnitude of exposure and the probability of occurrence of the health effects in question.
- Seeks answer to the question: What is the relationship between dose and incidence in humans?
- Second component of the U.S. EPA "Risk Assessment" process.

EXPOSURE ASSESSMENT (U.S. EPA)

- Determination of the extent of human exposure before or after application of regulatory controls.
- Seeks to answer the question: What exposures are currently experienced or anticipated under different conditions?
- Third component of the U.S. EPA "Risk Assessment" process.

RISK CHARACTERIZATION (U.S. EPA)

- Description of the nature and often the magnitude of human risk, including attendant uncertainty.
- Seeks to answer the question: What is the estimated incidence of the adverse effect in a given population?
- Fourth and final step of the U.S. EPA "Risk Assessment" process. It combines the Dose-Response characteristics and the Exposure Assessment to characterize carcinogenic or non-carcinogenic risk of single chemicals or mixtures.

RISK ASSESSMENT (U.S. EPA)

- Consists of the above four processes (i.e., Hazard Identification, Dose-Response Assessment, Exposure Assessment and Risk Characterization). It is followed by "Risk Management" which includes: development of regulatory options, the evaluation of public health, economic, social and political consequences of the regulatory options, culminating in agency decisions and actions.

** HAZARD IDENTIFICATION (H&W)

- Identification of effects capable of adversely impacting on health as a result of exposure to a substance.
- May utilize case reports, toxicological studies, epidemiological investigations or structure-activity analysis.
- First step in the Health and Welfare "Risk Assessment" process.

** RISK ESTIMATION (H&W)

- Involves quantitative estimation of the risk associated with the identified hazard.
- Involves quantitative analysis of epidemiological and toxicological data, as well as estimation of levels of human exposure. Examines the severity, extent and distribution of the effects, of an event or activity. Mathematical models are often used in Dose-Response extrapolations, especially in high to low dose and animal to human situations.
- Leads to a specific numerical point estimate or a range of values.
- Second step in the Health and Welfare "Risk Assessment" process.

OPTION EVALUATION (H&W)

- The process of developing and analysing options for the management of environmental hazards.
- Development of options may involve consideration of regulatory and non-regulatory approaches, and can range from the introduction of new regulatory controls, to economic alteration of program objectives, current institutional policies and the regulatory environment.
- Options Analysis may involve consideration of risks and benefits; uncertainties in risk estimation; public awareness and perception; technical feasibility; and economic, social, political and cultural impacts.
- Third step in the Health and Welfare "Risk Assessment" process.

** RISK ASSESSMENT (H&W)

- Consists of the above three H&W processes (i.e., Hazard Identification, Risk Estimation and Option Evaluation). For the purposes of this standard setting workshop and this session, Risk Assessment is considered to approximately include the tail end of the Hazard Identification, the Risk Estimation and perhaps the front end of the Option Evaluation components. Risk Assessment forms the basis of, and is followed by, Risk Management.

2 Other Pertinent Key Terms (in alphabetical order)

** ABSORPTION

- The penetration of a substance through a barrier (e.g., skin, gut or lungs).

** ACCEPTABLE DAILY INTAKE

- It is the daily intake of a substance, even over a lifetime which does not show any appreciable health risk.
- Often referred to as the no-observed-effect-level (NOEL) divided by some known safety factor.

** ACCEPTABLE RISK

- A risk which is so small, whose consequences are so slight, or whose associated benefits (perceived or real) are so great, that persons or groups in society are willing to take or be subjected to that risk.

** CANCER

- A group of diseases characterized by uncontrolled growth of body cells leading to formation of malignant tumours that tend to grow rapidly and spread.

** CARCINOGEN

- An agent capable of inducing a cancer response.

** CASE-CONTROL STUDY

- An epidemiological study in which individuals with the disease under study (case) are compared to individuals without the disease (controls).

** CONFIDENCE LIMIT

- An endpoint of a confidence interval. Confidence interval is that interval which has a specific probability of containing a given parameter or characteristic.

** DE MINIMIS RISK

- A risk is de minimis if it is considered trivial or negligible. In practical terms, when a risk is judged to be de minimis there is no incentive to modify the activity which gives rise to the risk.

** DELIVERED DOSE

- The amount or concentration of a substance at the site of action within the body.
- May involve consideration of metabolic activation processes, pharmacodynamics and tissue dosimetry.

** DOSE

- The amount or concentration of substance absorbed into the body. Usually expressed as mg per kg body weight. It is the fraction of the level of exposure to a chemical that actually enters the body following absorption (see exposure).

** DOSE-RESPONSE CURVE

- The graphic presentation of the relationship between the dose of a substance administered to a group of organisms and the frequency or magnitude of the biological effect (response). Dose is plotted on the x axis and response on the y axis.

** EPIDEMIOLOGY

- The study of the distribution and determinants of disease frequency in humans.
- May involve the observation of unusual clusters of a rare disease; descriptive statistics on morbidity and mortality patterns; ecological studies correlating disease occurrence rates with geographic or spatial risk factors; and analytical studies of the relationship between disease occurrence rates and exposure to particular hazards.

** EXPOSURE

- Contact between a substance and an individual or population.
- More precisely, the level of exposure to a substance is the amount of the substance in the vicinity of a portal of entry into the body (e.g., lung, mouth, skin) that may be available for absorption. Thus, normal exposure pathways are oral, dermal and inhalation.

** EXPOSURE CHARACTERIZATION

- Identification of the conditions of contact between a substance and an individual or a population.
- May involve identification of concentrations in various media (using monitoring or modelling data), routes of uptake, target sources, environmental pathways and population.

** EXPOSURE ESTIMATION

- Estimation of the amount and duration of contact between a substance and an individual or a population.
- May consider such factors as concentration, routes of uptake, target sources, environmental pathways, population and time-scale.

** EXTRAPOLATION

- The process of predicting the response of an organisms to some conditions of exposure to a substance based on the magnitude of the response seen at other conditions for exposure or in another species.

** INHALATION REFERENCE DOSE (RfD)

- An estimate (with uncertainty spanning perhaps an order of magnitude) of a daily exposure to the human population (including sensitive subpopulations) that is likely to be without appreciable risk of deleterious effects during a lifetime. RfDs are based upon a rigorously defined methodology within U.S. EPA.

** LOWEST OBSERVED ADVERSE EFFECT LEVEL (LOAEL)

- The lowest dose in a toxicity study that results in an observed adverse effect (usually one dose level above NOAEL).

** MAXIMUM LIKELIHOOD ESTIMATE

- A term used with mathematical models in quantitative risk assessment. It is the estimate of a value obtained using a statistical technique where the likelihood distribution is maximized (finding the largest value of a function is maximizing it).

** NO OBSERVED ADVERSE EFFECT LEVEL (NOAEL)

- The highest dose in a toxicological or epidemiological study which does not result in an adverse health effect.

** NO OBSERVED EFFECT LEVEL (NOEL)

- The highest dose in a toxicological or epidemiological study that does not result in any effect.

** 95 PERCENT UPPER CONFIDENCE LIMIT

- A term used with mathematical models in quantitative risk assessment. Confidence limit which states that the value in question has 5% probability of exceeding the true value.

** PHARMACOKINETICS

- Quantitative study of the metabolic processes of absorption, distribution to various tissues, biotransformation and elimination. Incorporation of such information in quantitative risk assessment may lead to a more accurate and less conservative estimate of the true dose producing a certain response. This in turn leads to a more accurate and less conservative prediction of risk.

** QUANTITATIVE RISK ASSESSMENT

- A term used loosely. It generally means the application of mathematical models to estimate virtually safe doses (VSDs) and/or unit risk.

** RISK

- A measure of both the probability of and hazard to health from exposure to a substance.

** STANDARD SETTING

- In the context of this session of the workshop, it is a process which includes coming up with a number, criteria development based on health effects and may include, in case of readily available data, consideration of exposure via several media through the use of added safety factors.

** UNIT RISK

- The incremental upper bound lifetime risk estimated to a result from a lifetime exposure to an agent if it is in the air at a concentration of 1 ug/m^3 or in the water at a concentration of 1 ug/L. Widely used by U.S. EPA. Obtained from mathematical models.

** VIRTUALLY SAFE DOSE (VSD)

- A dose which causes a very low risk of cancer. Preferred by Health and Welfare Canada. Obtained from mathematical models.
- Usually this risk is taken to be in the range of 10^{-5} to 10^{-7} over a lifetime.

** WEIGHT OF EVIDENCE CLASSIFICATION

- Classification approaches advocated by agencies like U.S. EPA and IARC for deciding whether an agent is a human carcinogen, probable human carcinogen, possible human carcinogen or not a carcinogen. This is based on the weight of evidence from human and toxicological studies. Primarily used for carcinogens. Closely related approaches, though less rigorously defined have been used in other toxicological areas. For example, in the area of mutagenicity, Rank Ordered categories of evidence are set up and used for deciding whether a substance is a potential human germ cell mutagen.

RISK ASSESSMENT IN NON–HUMAN BIOTA

S. ABERNATHY, K. JOHNSON

Risk Assessment In Non-Human Biota

The sub-group discussion topic was risk assessment for non-human biota. Discussion was initially directed by considering the following questions:

I. What are the Components of a Hazard Assessment?

1. Types of Hazards
   - toxicological
     - cell
     - single organisms
     - populations
     - communities
   - biomagnification

2. Aesthetics
   - taste
   - tainting
   - odour

3. Environmental Concentrations/Exposure
   - ambient and source specific

II. What is an Adverse Effect?

RECEPTOR	EFFECT
1. Aquatic Organisms Types of preferred data: fish >invertebrates >algae	- lethality - sublethality ° growth ° reproduction ° survival ° life stage - mutagenicity
2. Aquatic Communities	- changes in structure - species composition
3. Terrestrial	
a) Mammals	N/A
b) Plants *	- acute injury (foliage) - accumulation of nutrients/ non-nutrients - photosynthesis - reduced growth - % injury (not a LD_{50})

* Appendices A & B provide criteria used in standard setting for protection of terrestrial vegetation.

III. What are Some Problems in Extrapolation?

Aquatic Organisms	- few test species are available - acute vs chronic - lab vs field - acute lethality vs no effect
Plants	- suspended particulate vs deposition - seedling vs mature tree - lab vs field - chronic exposure poorly regulated

IV. How are Safety Factors Used?

Aquatic	- sliding scale based on data quality and quantity, and solubility properties of the substance. ° toxicity 8,000 - 13 ° bioaccumulation - 10 ° aesthetics - 2 ° mutagenicity - 10
Aquatic Community Impact	- no safety factor
Biota (aquatic)	- under development
Sediment	- no safety factor
Plants	- acute - 10 (see Upper Limits Guidelines in Appendices B & C)
Soil	- no safety factor (see Upper Limits Guidelines in Appendices B & C)

RECOMMENDATIONS

The following recommendations were developed out of the discussions and the set of directives provided by the senior management.

1. There should be a Ministry-wide standardization of reference terms and safety factors.

2. Partnerships and co-operation between jurisdictions should be encouraged.

3. Co-ordinated development of standards for the various media is desirable.

4. The objective setting process approaches for either an individual organism or ecosystem have their respective merits. Discussion aimed at integration of these alternatives should be undertaken.

5. It is desirable to develop standards for Ontario. Adoption by reference may be applied on a case-by-case basis.

6. The Ministry should assess the adequacy of activities and expertise in the terrestrial mammal area.

Summary (S. Abernethy)

The following problems were identified as common to most hazard and risk assessments:

1. Detection of biological change from chemical exposure does not necessarily indicate an adverse effect. Although toxic mechanisms are defined at the biochemcial and physiological level, the biological consequences for whole organism growth, survival and reproduction determines whether a given degree of effect is compensatory and adaptive or harmful. In addition, a toxic effect on an individual may or may not be significant to populations which are subject to large fluctuations due to starvation, disease, predation and abiotic environmental extremes.

2. Exposure is normally defined by both the magnitude, frequency, and duration of chemical concentration in various environmental media. However, measurement of ambient levels is indicative of exposure only when there is a direct relationship between degree of pollution and bioavailable dose at the site of toxic action.

3. Numerical criteria for the protection of life are always based on limited information. Available data are used to extrapolate from short exposures to full life cycles, from individuals to populations, from a few species to all species, from laboratory to field conditions and from severe or population effect to "no effect". Since there is no widely accepted method to reliably extrapolate, uncertainty exists and a margin of safety is generally employed.

   The toxicological criteria for standards are based upon the application of scientific judgement to limited data sets. This is evident from the fact that standards for some so-called "safe" chemical levels may differ between jurisdictions and are changed when more information becomes available. In some cases (eg. carcinogens) additional data may be interpreted to indicate that no "safe" level exists.

Standard-Setting for the Protection of Aquatic Life

Many of the recurrent problems associated with standard setting are addressed in MOEs process for setting Provincial Water Quality Objectives. Water Quality Objectives and Guidelines are numerical criteria designed to protect all forms of aquatic life at all stages in an aquatic life cycle during indefinite exposure. By this definition there is no concept of "acceptable" risk or degree of risk. Guidelines are treated as the best available approximation of a single "safe" number for aquatic environmental protection. Risk management is thus simplified and is always separate from the number-setting process. This is a practical, operational approach, necessary because the numbers are used as assessment tools in pollution control.

Specifically, Guidelines and Objectives provide a numerical basis for establishing industrial and municipal wastewater discharge limits and are used to interpret data on the concentration of substances in effluents and receiving waters. If concentrations of a given chemical significantly exceed the Guideline, a potential water pollution problem is flagged. This helps the Ministry identify priorities for management decisions and action, and provide dischargers and abatement managers with a planning tool.

The development of a Provincial Water Quality Guideline follows a prescribed series of steps, that help ensure consistency in the interpretation and use of data for setting numerical values. A Guideline is calculated by applying a conservative safety factor called a "final uncertainty factor" to the lowest water concentration shown to cause a deleterious effect. The size of the safety factor is based on the chemical's octanol-water partition coefficient and the comprehensiveness of the available toxicity information.

As new toxicity data become available, Guideline values will be periodically reassessed and, if warranted, modified using the Ministry's Objective setting process (when a minimum information base of high quality toxicity data is available). The type of toxicity information which generates the lowest uncertainty factor and/or supports the promotion of a Guideline to an Objective is defined and discussed in the Objectives setting document.

Standard-Setting for the Protection of Terrestrial Life

Hazard and risk assessment for environmental protection was considered more difficult and less advanced for terrestrial than for aquatic systems. Similar complications and problems (i.e. scientific uncertainties) occur in assessing terrestrial and aquatic situations, the difference is primarily one of degree.

The following problems were identified as particularily difficult in terrestrial situations:

- airborne chemical exposure is so variable in time and space that exposure is difficult to quantify.
- data collection re: chronic effects.
- for many terrestrial plant species, there is no accepted standard measure of acute toxicity, analogous to the aquatic LC_{50}?

APPENDIX A

Standard Setting for the Protection of Terrestrial Vegetation

Terrestrial vegetation is protected (and so too, those who consume it) through three general vehicles: (a) the standards, ambient air quality criteria, tentative design standards, guidelines and provisional guidelines as recommended by the Environmental Air Standards Setting Committee (EASSC); (b) M.O.E. "Upper Limit of Normal" contaminant guidelines for Phytotoxicology Samples; and, (c) soil clean-up guidelines for decommissioning of industrial lands. Each is discussed here, in turn.

(a) Regulated and other EASSC recommended air concentration limits

In the printed listing of the standards, ambient air quality criteria (AAQC), tentative design standards, guidelines and provisional guidelines provided by George Nagy at the standards setting processes workshop, the limit for each element or compound is categorized according to the known Limiting Effect, whether it be health, odour, corrosion, soiling, irritant, visibility or vegetation effects. Although the number of air quality recommendations, which are based in part or whole on vegetation effects, is relatively small (compared say to human health), the known phytotoxicants are among the most common pollutants. These include: chlorine, ethylene, fluoride, nickel, ozone and sulphur dioxide; and should probably include nitrogen oxides.

In most cases, standards or AAQC's (which are up-to-date and provide good, or at least satisfactory, protection for vegetation) exist for these phytotoxic air pollutants for short-duration (acute) exposures. The Ontario AAQC of 1 ppb fluoride for 24 hours provides barely adequate protection for sensitive vegetation, yet is being challenged in the United States as too stringent. A National Ambient Air Quality Objectives document, prepared by a joint Federal/Provincial Committee and using in part, Phytotoxicology controlled environment data, defends this 24 hour level. The chlorine standard probably needs no review. The ethylene design standard provides adequate protection for vegetation for short duration exposures but is largely inadequate for protection from longer term exposures. Although ozone is very well worked there is a continuing debate over how the standard(s) should be expressed; i.e. the time-averaging period, and whether short-duration, high-concentration exposures are more or less important than

longer-duration, lower-concentration exposures. Nickel and sulphur dioxide (dry deposition) are properly regulated. On the other hand, nitrogen oxide criteria probably do not provide adequate protection for vegetation when present in combination with other pollutants.

As noted with regard to certain specific pollutants above, short (time) duration standards exist for many if not most phytotoxic air pollutants. Chronic exposures however are very poorly regulated.

Major knowledge and/or regulatory gaps exist for other phytotoxic pollutants. These include hydrogen chloride and a number of inorganic salts including sodium chloride and sodium borate. Hydrogen chloride is regulated for short-term exposure by a 24 hour AAQC of 40 $\mu g/m^3$. However, there is no provision for regulating long-term exposure (30 days or more) such as will occur in the vicinity of waste incinerators. Sodium chloride causes more economic damage than most of the other pollutants combined, yet is ignored in regulation. Severe damage to vegetation has been documented around a number of sodium borate sources in Ontario, yet no relevant regulatory limits exist.

The operative word in the above line is "relevant". Most standards , criteria, etc. are, quite understandably, people oriented - they were established to protect humans first. This is most evident in the manner in which they are expressed; i.e. they are almost exclusively expressed as air concentrations, either as a concentration of gas or weight/unit volume of suspended particulate. Plants, however, are affected by that which falls on their foliage and the soil in which they grow. Water bodies are contaminated by that which is deposited to their surfaces or to surfaces within their watershed. Materials are corroded by that which touches or falls upon their surface. Our well deserved attention to acid precipitation represents the first major recognition that deposition is as critical as that which remains suspended or in solution in the atmosphere. If we expect to offer our natural environment adequate protection, we must address pollutant deposition.

In general, standards, criteria, etc. are established to protect the most sensitive receptor in the environment. Where the most sensitive receptor is judged to be vegetation, the choice of plant upon which the standard is set is usually based on some prior knowledge of relative sensitivities of vegetation to the pollutant in question, or a pollutant with similar

chemical properties. For instance bean species are generally sensitive to salts, making pinto, broad or soybean a common choice for further experimentation.

(b) "Upper Limit of Normal" Contaminant Guidelines

Please refer to the attached draft of a document entitled: "Ontario Ministry of the Environment 'Upper Limit of Normal' Contaminant Guidelines" which is currently being reviewed for publication.

(c) Soil clean-up guidelines for decommissioning of industrial lands

Please refer to the attached extract from a document entitled: "Soil Clean-up Guidelines for Decommissioning of Industrial Lands, Background and Rationales for Development" which will shortly be submitted for Divisional Management Review.

February 21, 1989

Ontario Ministry of the Environment "Upper Limit of Normal" Contaminant Guidelines for Phytotoxicology Samples

DRAFT

Phytotoxicology Section

Air Resources Branch

Technical Support Sections

NE and NW Regions

ARB No.: ARB-138-88-Phyto

Date : December 1988

Ontario Ministry of the Environment "Upper Limit of Normal" Contaminant Guidelines for Phytotoxicology Samples

Background

The Phytotoxicology Section of the Air Resources Branch, in concert with associates from the Northeastern and Northwestern Regions, recognized in 1971 a need to establish contaminant concentration guidelines for interpretation of environmental data. Utilizing the results of chemical analyses and available toxicological information, guidelines which were termed "Concentrations Considered Excessive" were developed for a number of contaminants in soil and plant foliage. These guidelines were utilized in Phytotoxicology investigations, with periodic revisions as deemed appropriate, notably in 1978 and 1982.

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By early 1983, it had become apparent that the processes by which the Phytotoxicology guidelines had been established to date were less than satisfactory, because they varied among contaminants, were too subjective, and could not be supported by any consistent procedure or mathematical model.

After discussion among Phytotoxicology and Regional staff, it was agreed that new guidelines should be developed which would have a consistent mathematical basis and which could be used to distinguish

contaminated from uncontaminated situations. To this end, efforts were directed toward assembling a data base of analytical results for environmental samples collected from "background" (i.e. non-point source-contaminated) areas of Ontario.

Concurrently with these developments, a large-scale review of Ontario Regulation 308 (Air Pollution - General Regulation) was initiated by the Ministry of the Environment. One of the tasks of the review was the following: "Determine if Phytotoxicology standards, criteria or guidelines should be established for soil (and vegetation) deposition. Should they be incorporated in Reg. 308 or developed into a guideline?"([1]). A committee with Air Resources Branch and Regional representatives was established to examine this issue. The committee proceeded along the lines previously initiated, and developed "Upper Limit of Normal" (ULN) contaminant guidelines for terrestrial samples collected in Ontario. The concept and philosophy of the proposed Phytotoxicology ULN guidelines were than discussed at a Reg. 308 Workshop held in Toronto in November, 1985([2]). The decision was made that ~~that~~ the ULN guidelines, being statistically derived and subject to modification as new data are generated, not be incorporated in Reg. 308 but be published as a reference document([3]).

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Derivation and Significance of ULN Guidelines

The MOE Upper Limit of Normal contaminant guidelines are shown in the attached table. The guidelines essentially represent the expected maximum concentrations of contaminants in surface soil (non-agricultural), foliage (deciduous and current year coniferous trees and shrubs), grass, moss bags and snow from areas of Ontario not subject to the influence of point sources of emissions. "Urban" guidelines are based upon samples collected from centres of minimum 10,000 population. "Rural" guidelines are based upon samples collected from non-built-up areas. All samples were collected and processed by MOE personnel using standard techniques(4). Chemical analyses were performed by the MOE Laboratory Services Branch(5).

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The guidelines were calculated by taking the arithmetic mean of available analytical data and adding three standard deviations of the mean. For those distributions that are "normal", 99% of all contaminant concentration results for samples from "background" locations (i.e. not affected by point sources nor agricultural activities) will lie below these upper limits of normal. For those distributions that are "non-normal", the calculated upper limits of normal will not actually equal the 99th percentile; however, they lie within the observed upper range of MOE results for Ontario samples. Geometric means were not employed in calculating the guidelines

because: 1) tests of two representative non-normal distributions showed that normality was not significantly improved by using log-transformed data, and 2) the guideline concentrations calculated using the geometric mean were considerably higher than the maximum observed concentrations.

Due to the large variability in element concentrations which may be present across Ontario, even in background data, control samples should always be collected. This is particularly important for soils, which may show large regional variations in element composition due to differences in parent material. Species of vegetation which naturally accumulate high levels of an element also may be encountered and, as with soil samples, will require careful interpretation and comparison with controls to avoid erroneous conclusions regarding environmental contamination.

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It is stressed that these guidelines do not represent maximum desirable or allowable levels of contaminants. Rather, they serve as levels which, if exceeded, would prompt further investigation on a case by case basis to determine the significance, if any, of the above-normal concentration(s). Concentrations which exceed the guidelines are not necessarily toxic to plants, animals or man. Concentrations which are

below the guidelines would not normally be considered toxic. A brief review of world literature has shown that the guideline concentrations are generally within the respective ranges of results reported by other investigators.

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The table of guidelines will be expanded and revised as more data become available.

RE2754

References

(1) Duncan, C.E. 1983. Proposal for a Review of Air Regulations. Mimeographed Report. Air Resources Branch, Ministry of the Environment.

(2) Ontario Ministry of the Environment. 1986. Proceedings of Air Pollution General Regulation Workshop, Nov. 14th/15th, 1985.

(3) Ontario Ministry of the Environment. 1987. Stopping Air Pollution at its Source: Clean Air Program - Discussion Paper.

(4) Ontario Ministry of the Environment. 1983. Field Investigation Manual. Phytotoxicology Section - Air Resources Branch; Technical Support Sections - NE and NW Regions.

(5) Ontario Ministry of the Environment. 1983. Handbook of Analytical Methods for Environmental Samples, Vols. 1 & 2. Laboratory Services Branch.

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to the mean of the data plus three standard deviations.

Parameter	Soil (0-5 cm) Urban	Soil (0-5 cm) Rural	Foliage (unwashed) Urban	Foliage (unwashed) Rural	Grass (unwashed) Rural	Moss Bags** Urban	Moss Bags** Rural	Snow*** Rural
Aluminum	a	a	500***	500	a	a	1700	0.5
Antimony	8	1**	0.5**	0.3**	a	2	a	a
Arsenic	20	10	2	0.5,2*	c,8*	2	1	0.03
Boron	15	10**	175	75	20	a	a	a
Cadmium	4	3,4*	2*	1*	0.5,2*	4	2	0.003
Calcium	b	b	a	3%	a	a	a	2
Chloride	a	a	b	0.15%	1%	a	0.03%	?
Chromium	50	50	8	8	5	7	a	0.003**
Cobalt	25***	25	2***	2	2,8*	6	a	0.01**
Copper	100	60	20	20	7, 20*	60	8	0.06
Fluoride	a	a	35	15	12	a	45	0.1**
Iron	3.5%***	3.5%	1000	500	500	3000	1700	0.7
Lead	500	150	60	30	20	200	35	0.05
Magnesium	a	1%	0.7%	0.7%	a	a	a	0.4
Manganese	700	700,1000*	100	b	50,a*	a	a	0.02
Mercury	0.5	0.15	0.3	0.1	a	a	0.2	0.0001**
Molybdenum	3	2**	1.5	1.5	6	a	a	a
Nickel	60***	60	7	5, 30*	5,25*	13	6	0.04
Nitrogen	a	a	b	b	a	a	a	3 (as nitrate)
Phosphorus	a	a	a	a	a	a	a	0.15
Potassium	a	d	a	a	a	a	a	1
Selenium	2	2	0.7	0.5	0.5	a	0.6	c
Silver	c	a	a	a	a	a	a	a
Sodium	a	a	350	50	[illegible]	a	b	2
Sulphur	a	0.1%	0.4%	0.4%	0.6%	a	0.1%	3 (as sulphate)
Vanadium	70	70	5***	5	6	a	c	a
Zinc	500	500	250***	50	40,100*	800	100	0.3
Alkalinity	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	5.5
Conductivity	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	45
Suspended Solids	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	25
Dissolved Solids	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	30
Total Solids	n.a.	na.	n.a.	n.a.	n.a.	n.a.	n.a.	40
Dissolved Organic Carbon	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	2
Dissolved Inorganic Carbon	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	1
Total Particulate Carbon	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	7

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Notes:

* Where two values are shown, the first is based mainly on Southern Ontario data while the second is based on NE Region data. Also, there are indications that some of the guidelines, at least for foliage, may be somewhat liberal for the NW Region. THESE GUIDELINES ARE MEANT TO SUPPLEMENT, RATHER THAN REPLACE, SPECIFIC CONTROL DATA.

** Provisional guideline estimated from range of results, pending additional data.

*** Rural results higher than urban results - urban guideline based on rural results.

* Data for species considered to be accumulators (Populus spp., Salix spp., Betula spp.) excluded.

** Moss bag guidelines based on 30 day exposure. No data from NE region.

*** Snow guidelines are mg/l of meltwater, except conductivity which is µmhos/cm. Based mainly on NW and NE Region data.

a Sample size insufficient (<30) to establish guideline.

b Concentration highly variable - guideline not established.

c 50% or more of results less than detection limit - guideline not established.

d Discrepancy between Ontario data and literature values - guideline not established.

n.a. Not applicable (no data).

APPENDIX C

Soil Clean-up Guidelines for Decommissioning of Industrial Lands - Background and Rationales for Development

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Phytotoxicology Section

Air Resources Branch

ARB No: ARB-207-88-PHYTO

Author: R. J. Rinne

Date: [redacted]

Soil Clean-up Guidelines for Decommissioning of Industrial Lands - Background and Rationales for Development

BACKGROUND

In February, 1984, the Phytotoxicology Section was requested by the Halton-Peel District Office of the MOE to provide input into the development of soil guidelines for the decommissioning of oil refinery lands. Considerations of proposed land use made it desirable to have separate criteria for residential and industrial redevelopment. One of the oil companies involved had retained the services of Monenco Consultants. Monenco undertook a large-scale literature survey in an attempt to relate contaminant concentrations in soil to toxic effects on vegetation, animals and man. As a result of this effort, Monenco was able to recommend site-specific soil clean-up criteria for a number of contaminants (Monenco Ontario Ltd., 1984a & 1984b). The Phytotoxicology Section critically reviewed Monenco's proposals. In some cases, the clean-up levels suggested by Monenco were supported by information available to the Phytotoxicology Section, and were therefore deemed to be acceptable to the MOE. In a number of cases, however, the clean-up criteria initially recommended by Monenco were unacceptable to the Phytotoxicology Section. Most of the disagreements were resolved at a series of meetings involving the oil companies, Monenco Consultants and the MOE (Halton-Peel Office and Phytotoxicology Section). However, in a limited number of cases, the clean-up levels recommended by the Phytotoxicology Section were regarded as somewhat conservative by Monenco Consultants. Also, Monenco Consultants did not provide input to all of the recommended guidelines. The Halton-Peel District MOE office is satisfied that the clean-up guidelines recommended by the Phytotoxicology Section are both reasonable and defensible.

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Subsequent to the above-described exercise, the Phytotoxicology Section was requested by Halton-Peel District MOE to recommend clean-up guidelines for additional contaminants. Provisional guidelines for these additional elements were developed, based on a literature review.

The guidelines and provisional guidelines were reviewed and approved by the Health Studies Service, Special Studies and Services Branch of the Ministry of Labour and by the OMAF/MOE/MOH Sludge and Waste Utilization Committee.

More recently, the Phytotoxicology Section was requested by the MOE Waste Management Branch to develop clean-up levels for agricultural land use. This request was brought to the attention of the Sludge and Waste Utilization Committee. It was the opinion of this Committee that the residential/parkland clean-up levels previously developed were, with minor modifications/qualifications, also suitable for application to agricultural situations.

The clean-up guidelines and provisional guidelines as established in this manner have been adopted by the Phytotoxicology Section as recommended clean-up levels with potential general application in the decommissioning and redevelopment of industrially-contaminated sites in Ontario. The clean-up levels have been incorporated in the Waste Management Branch policy document, "Guidelines for the Decommissioning and Clean-up of Sites in Ontario", which has recently received formal approval and will be published shortly.

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RATIONALES FOR DEVELOPMENT

The soil clean-up guidelines recommended by the Phytotoxicology Section for industrial site decommissioning are shown in attached Table 1. The rationales fo their development involved considerations of phytotoxicity, animal health, and human health. In general, the most conservative of these considerations was used to established a residential clean-up level. Redevelopment as parkland also was felt to warrant this conservative approach, because parkland often is used as play areas by children, and occasionally is used for allotment gardening. Different industrial/commercial clean-up levels (normally set at twice the residential levels) were recommended where the

residential and industrial criteria were both set on the same basis (i.e. phytotoxicity or human health), but where phytotoxic or health concerns were judged to be considerably less significant in the industrial than in the residential situation. For two elements (molybdenum and selenium), residential clean-up levels were established to prevent toxicity to grazing animals, whereas a higher industrial level was established to prevent toxicity to vegetation. Where assurances can be had that land will not be used for production of animal feed (probably most residential situations), the animal health based guidelines need not be applied.

Provisional clean-up guidelines recommended by the Phytotoxicology Section for four contaminants are found in attached Table 2. Because knowledge of potential adverse effects of these elements in soil is generally more limited than for the Table 1 guidelines, the provisional clean-up levels were purposefully established in an even more conservative vein. (The terms "guideline" and "provisional guideline" are defined in Appendix 1).

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A discussion of possible interactive effects (antagonistic, additive or synergistic) of soil contaminants is found in Appendix 2.

These clean-up guidelines and provisional guidelines are considered to be suitable for direct application in the majority of industrial site clean-up scenarios that may be encountered in Ontario. However, since the mobility and availability of metals in soils may be highly dependent on form of the metal, soil texture, pH and organic matter content, site-specific considerations of these parameters may reveal the suitability of different criteria. For example, where metals are known to be present in specific forms of very limited availability, higher clean-up levels may be considered. Furthermore, in researching the clean-up criteria, Monenco Consultants utilized data from studies on medium to fine textured soils (i.e. sandy soils excluded), in which mobility (availability) of metals would be lower

than in coarse-textured sand (hence, metals are less likely to accumulate in sand than in clay). Therefore, it is recommended that the clean-up levels for the metals and metalloids be reduced in the case of coarse-textured (greater than 70% sand) mineral soils (less than 17% organic matter). This recommendation is reflected in the clean-up levels shown in Tables 1 and 2.

Recommended Depth of Clean-up

The Phytotoxicology Section recommends that, in areas not to be permanently covered over, contaminant concentrations in at least the top 30 cm of soil on a decommissioned industrial site should meet the clean-up guidelines (as measured in any 5 cm soil increment). Site-specific factors may necessitate a greater clean-up depth. For example, where phytotoxicity to deep rooted trees is a concern, clean-up to a depth of 2 m may be required. Also, the possibility of surface and/or groundwater deterioration may indicate the need for even greater depths of clean-up (although this factor is normally measured using a leachate extraction procedure rather than total metal concentrations in soil).

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Rationales for Guidelines (Table 1)

The rationales for the individual parameters are summarized in point form below (concentrations are given as ppm (ug/g), dry weight, unless otherwise indicated).

Soil pH

- range as generally amenable to good plant growth is pH 6 to 8 (i.e. slightly acidic to slightly alkaline)
- at pH < 6, availability of metals may increase such that phytotoxicity could occur even if total metal concentrations were below clean-up levels

Table 1
Clean-up Guidelines for Soils

Parameter[b]	Criteria for Proposed Land Use[a,c]			
	Residential/Parkland/ Agricultural[d]		Commercial/Industrial	
	Medium & fine Textured Soils	Coarse Textured Soils[e]	Medium & Fine Textured Soils	Coarse Textured Soils[e]
pH (recommended range)	6-8	6-8	6-8	6-8
EC (mS/cm)[h]	2	2	4	4
SAR[i]	5	5	12	12
Arsenic	25	20	50	40
Cadmium	4[a1]	3[a1]	8[a1]	6[a1]
Chromium (VI)	10	8	10	8
Chromium (total)	1000	750	1000	750
Cobalt	50	40	100	80
Copper	200[a2]	150[a2]	300	225
Lead	500[a1]	375[a1]	1000[a1]	750[a1]
Mercury	1[a1]	0.8[a1]	2[a1]	1.5[a1]
Molybdenum	5[a2]	5[a2]	40	40
Nickel	200	150	200	150
Nitrogen (%)	0.5[f]	0.5[f]	0.6[f]	0.6[f]
Oil and Grease (%)	1[g]	1[g]	1[g]	1[g]
Selenium	2[a2]	2[a2]	10	10
Silver	25	20	50	40
Zinc	800	600	800	600

Notes:

a. Clean-up guidelines recommended by the Phytotoxicology Section, Air Resources Branch, Ministry of the Environment. The guidelines are based primarily on phytotoxicity, except for (a^1), based on human health, and (a^2), based on health of grazing animals.

b. All units are in ppm (ug/g), dry weight, unless otherwise stated.

c. For comparison with these guidelines, analyses for metals and metalloids must be conducted using an approved strong, mixed-acid digestion procedure. Contact the Laboratory Services Branch of MOE if in doubt about acceptable methods.

d. Guidelines have been endorsed by the OMAF/MOE/MOH Sludge and Waste Utilization Committee.

e. Defined as greater than 70% sand and less than 17% organic matter.

f. If N levels exceed the guidelines, the mineralization potential of the soils should be evaluated. Additions of N-based fertilizer may be counter-productive.

g. Guideline given is for fresh oil; for weathered oil (min. 2 yr. exposed on site), the guideline is 2%.

h. EC = electrical conductivity (saturation extract).

i. SAR = sodium adsorption ratio.

RE4272-TAB

Table 2
Provisional Clean-up Guidelines for Soils

Parameter[b]	Criteria for Proposed Land Use[a,c,d]			
	Residential/Parkland/Agricultural[e]		Commercial/Industrial	
	Medium & fine Textured Soils	Coarse Textured Soils[f]	Medium & Fine Textured Soils	Coarse Textured Soils[f]
Antimony	25	20	50	40
Barium	1000	750	2000	1500
Beryllium	5	4	10	8
Vanadium	250	200	250	200

Notes:

a. These guidelines are tentative; actual permissible levels of contaminants may vary according to site-specific circumstances. Further information on the application of these guidelines may be obtained from the Phytotoxicology Section of the Air Resources Branch, Ministry of the Environment.

b. All units are in ppm (ug/g), dry weight.

c. For comparison with these guidelines, analyses must be conducted using an approved strong, mixed-acid digestion procedure. Contact the Laboratory Services Branch of MOE if in doubt about acceptable methods.

d. These provisional guidelines apply to soil of minimum pH 6.

e. Guidelines have been endorsed by the OMAF/MOE/MOH Sludge and Waste Utilization Committee.

f. Defined as greater than 70% sand and less than 17% organic matter.

RE4272-TAB

INTEGRATED STANDARD SETTING AND MULTIMEDIA CONCERNS

B.THORPE,B.WORTHINGTON

INTEGRATED STANDARD SETTING AND MULTIMEDIA CONCERNS

DISCUSSION GROUP

REPORT TO PLENARY SESSION

I. Process of Group Discussion

Initially, the group brainstormed to identify issues related to integrated standard setting and multimedia concerns. The 22 issues identified by the group are listed in Table 1. The issues were reviewed and grouped into six categories according to their degree of interrelatedness. Each group of issues was given a representative title which is listed in Table 2. The six topics were ranked by each member of the group by assigning a number from one to six: one being the most important topic for discussion and six being the least important. The group score was then tallied for each category. The group had time to discuss only the two most important topics (A and B in Table 2).

Table 1

Issues Identified During Group Discussion Related to Integrated Standard Setting and Multimedia Concerns

1. What is the legislative basis or mandate for a multimedia approach?
2. What are the respective standard setting responsibilities in MOE branches in relation to each other?
3. There is a need for standardized MOE standard setting for all media.
4. Should a single, centralized standard setting agency within MOE be established?
5. How can the co-operation of all groups involved in a multi-year project be ensured?

6. Is the database adequate or is the task of setting multimedia standards impossible?
7. Although the potential for multimedia exposure is known to exist for specific chemicals, it is often difficult to know the extent of human exposure via air, drinking water, food, etc. The information on exposure pathways is generally not in the toxicological literature. Therefore, allocation of the acceptable daily intake amongst the various media is difficult.
8. Multimedia standards compound the problems of error factors. Data gaps may confound the situation to the point where it is impossible to proceed further in standard development.
9. Data acquisition/assessment should be in-house; consultants used to date have not been very good and, therefore, should not be used.

10. What is the effectiveness of a multimedia versus a single medium approach?
11. There is a problem of differing priorities of chemicals with respect to standard setting amongst different groups.
12. When is multimedia standard setting the best approach? Not all pollutants need a multimedia approach. The multimedia approach should be selective not exhaustive, i.e., based on the contaminant's properties and use in the province.

13. How important is the aquatic environment and biota in the multimedia approach?
14. From the aquatic perspective, a subsidiary multimedia approach might be appropriate in which the transfer of a contaminant from air to water to sediment to fish would be considered. How would this approach mesh with the approach currently used?
15. Can more multimedia pathways be included, e.g., non-human?
16. Is a multimedia approach amenable to ecosystem effects?
17. Could waste be considered an exposure sub-pathway?

18. Should occupational exposure be considered in multimedia standards? Should non-occupational exposure to indoor air be considered in multimedia standards?

19. If one group which is establishing a human health-based standard for a single medium, e.g., air, uses all of the acceptable daily intake (ADI) then groups which set standards for other media, e.g., drinking water, are limited. Competition for the ADI amongst groups can result in conflict.

20. There is a need for new approaches for allocation not just with HCCB contaminant projects.

21. Individuals involved in standard setting work in a vacuum; pertinent information should be shared.

22. To date, the multimedia documents produced by the Hazardous Contaminants Coordination Branch (HCCB) of the Ministry of the Environment (MOE) have been large and time-consuming. Is there a way of making a smaller or quicker multimedia assessment?

Table 2

Potential Topics for Discussion
(in order of decreasing priority)

A. Coordination of the Ministry of the Environment standard setting process (Issues 1-5 listed in Table 1)

B. Feasibility of developing multimedia standards given incomplete databases (Issues 6-9 listed in Table 1)

C. Identification of candidate substances for the multimedia approach (Issues 10-12 listed in Table 1)

D. What should be the scope of a multimedia criteria document? (Issues 13-18 listed in Table 1)

E. Information/data transfer and allocation issues (Issues 19-21 plus 4 and 11 from Table 1)

F. Fast-track of multimedia approach (Issue 22 from Table 1)

II. Details of Group Discussion

The following is a summary of the range of issues discussed between group members. It does not represent a consensus of opinion on the issues raised. This is found in Section III of the report. Topics A and B from the list in Table 2 were discussed.

A. Coordination of MOE Standard Setting Process

The expected gains from coordination of MOE standard setting are:

1) a reduction in the duplication of effort in obtaining data;
2) consistent risk assessment;
3) better standards;
4) better environmental protection;
5) better public acceptance of standards.

There was a feeling amongst group members that many problems which may arise from the coordination of the MOE standard setting process would be of a political nature.

A single, centralized agency responsible for standard development throughout MOE was seen as being an organization where little progress would be made because of the time-consuming nature of the process. At the branch level, a faster response could be achieved with a larger number of small products and a better chance of success. The discussion leader challenged the group to define "success" with regard to standard setting but no definition was offered by any member.

A need may exist for a standardized standard setting process.

Could the potential for multimedia exposure be considered in the development of all single medium standards? For example, would it be possible to adopt a standard protocol for allocation of a certain percentage of the exposure to air, drinking water, food, etc.?

In developing a standard for drinking water or air, the same toxicological literature would be considered. However, the information necessary to establish aquatic standards resides in a separate database. In the multimedia approach, aquatic contaminants should be considered at a later stage. There was some concern that air standards should consider aquatic deposition and sediment, e.g., in the case of aluminum, benzene, lead and polychlorinated biphenyls (PCBs). The reverse process also occurs; PCBs are known to migrate from large bodies of water to air. Therefore, it is important to consider all possibilities of intermedia transfer. It was realized that this is a difficult issue because of the long-range transport of contaminants.

Currently, there are a variety of approaches to standard setting within the MOE. Each group involved in standard setting is directed by a different mandate or legislation, e.g., Regulations 308 and 309, Ontario Water Resources Act, etc. Legislative tools such as Certificates of Approval and control orders exist to enforce the standards. No legislation currently exists for HCCB activities. There was a question of whether there is a need for legislation for HCCB.

Is a formal MOE policy necessary for standard setting?

Each branch prioritizes chemicals in a different manner. Individuals involved in standard setting need to know what other standard-setters are doing to decide when to interact and, if necessary, adopt a consistent approach.

B. Feasibility of Developing Multimedia Standards Given Incomplete Databases

In some cases, it is necessary to adopt a multimedia approach. In other instances, such as emission of a chemical from a single source, a multimedia standard is not needed. Of importance, there is a need for the Ministry of the Environment to develop a policy which describes the circumstances under which a multimedia approach should be used.

Currently, data gaps exist in the literature with regard to both the level of contaminants in various media and their toxicology. This lack of data should not prevent the development of standards. A strategy to deal with data gaps must be developed, if only as a interim measure, until appropriate allocations are known. Estimates of environmental exposure can be made based on information such as physical/chemical properties, quantities in use and geographic distribution of the source(s).

Existing standards must be reviewed on a regular basis to ensure that any new toxicological information and exposure data are incorporated into the standards, if necessary. With the large amount of data which is being generated in this area, particularly with respect to certain chemicals, this can be a difficult undertaking.

There is a need for a Central Registry of MOE-generated standards on computer. For each chemical, the following information should be included: the standard, i.e., chemical concentration; date of development; MOE contact; reference to rationale document; receptor and endpoint of concern; medium(a); and status (in progress; draft; completed). It was noted that HCCB had a Request for Purchase for the development of a Central Registry in their 1987-88 budget. However, it is expensive to establish such a registry (estimated cost was $60,000) and the project was not contracted out. In the development of a Central Registry, there is a need to be confident that the database is correct.

There was concern that the multimedia approach appears to try to protect all receptors with one objective which is then allocated to the different media. It would seem to make more sense to protect the separate target areas first and then correlate the information if one target area interacts with another. This

approach could reduce the scope for some receptors where the pathways are not linked. It was emphasized that in the multimedia documents produced by HCCB, the total number established for a contaminant is not meant to protect all receptors. Water quality may be set on bioaccumulation of a contaminant in fish, whereas health effects are based on human exposure.

The use of consultants to provide information may not be cost-effective because of the time required to manage consultants and because their work may not be accurate.

III. Summary of Group Discussion

It was the task of the group leader, rapporteur and facilitator to summarize the group discussion. The summary was reviewed and amended, as necessary, by the group as a whole. The most important issues were determined and the pros and cons of each topic discussed were listed:

A. Coordination of MOE Standard Setting Process

Should MOE Standard Setting Process be Coordinated?

i) **Standardized Generic Approaches Applicable to Any or All Media** (air, water, soil, vegetation, etc.)

CONS:
* would require time to develop protocol
* question whether approach can be applied to a broad range of chemicals

PROS:
* reduce duplication if information is shared
* better public understanding and acceptance of standards
* help ensure standard setting staff interact with each other
* could help information transfer on new standard setting approaches: Example (1), standardize protocols for consideration of multimedia exposure and allocation for various classes of compounds; Example (2), new developments in understanding atmospheric deposition to water could be considered in setting air standards and vice versa

ii) **Computerized Centralized Registry of MOE Standards/ Guidelines including information on standards: e.g., concentration; date established; MOE contact; reference to rationale document; receptor and endpoint of concern; medium(a); status (in progress; draft; completed)**

CONS: * cost to establish

* time consuming to set up

* requires ongoing upkeep and maintenance

* who takes charge

* need good MOE contact/liaison

PROS: * time saving for staff subsequently working on same contaminant

* important for monitoring/enforcement staff and Spills Action Centre

* reduce potential duplication of effort

* could serve other Ministries, students, researchers

* ideally should eventually be expanded to include other agencies' standards and guidelines (federal/ international)

iii) **Centralized Agency to Develop MOE Standards**

CONS: * time-consuming; slow to react

* variety of MOE needs which require different priorities and expertise

* variety of legislative bases and mandates makes it difficult to roll the responsibility of setting standards into one agency

* establishing a centralized agency would cause major staff disruption

* technical experts could lose expertise because they are not currently involved in standard setting on a full-time basis but would be in a centralized agency

PROS: * better coordination and information transfer

* clarify roles, e.g., regions/public/approvals would have MOE contact

* should reduce duplication of information and expenditure

* easier to develop consistent approaches and policies

B. Feasibility of Developing Multimedia Standards Given Incomplete Databases

CONS: * multimedia approach tries to be inclusive - in considering aquatic contamination, the data has to be reviewed again from a different perspective, i.e., not from the perspective of human health; it is too large an area to cover both human and environmental receptors but where they overlap both should be considered

* potential for magnification of errors when data gaps are in many different media and fields

* may delay to get missing data, therefore, the process could be slower

PROS: * never enough data whether single medium or multimedia

* even when data gaps exist, multimedia approach is more realistic of what actual environmental exposures are. It is possible to make estimates of exposure based on information such as physical/chemical properties, quantities in use and geographic distribution of sources.

* in the future, the research/monitoring required to alleviate data gaps can be targeted

IV. General Conclusions

Two general conclusions were reached by the discussion group:

1. Consultants are not the solution to fast-tracking standards because they require extensive technical supervision and time to manage. Consultants may not be cost-effective and may not deliver quality products.

2. There was insufficient time in our discussion group to fully develop all of the issues identified during the brainstorming period. The Standard Steering Committee may wish to have working groups develop these issues at a later date.

V. Recommendations

After careful consideration, the following two recommendations were offered by the discussion group:

1. Standardize the approach of the Ministry of the Environment to standard setting by:

   a) developing generic protocols for standard setting applicable to any or all media

   b) establishing a centralized computer-based registry of Ministry of the Environment standards, guidelines, objectives, etc.

2. A multimedia approach should be used for specific contaminants where there is consensus on the need and evidence of multimedia exposure and risk.

PUBLIC PARTICIPATION AND THE ADVISORY COMMITTEE ON ENVIRONMENTAL STANDARDS

R.R.WEILER,D.EVANS

SUMMARY OF DISCUSSIONS CONCERNING PUBLIC PARTICIPATION AND THE ADVISORY COMMITTEE ON ENVIRONMENTAL STANDARDS, HELD AT THE STANDARD SETTING WORKSHOP FEBRUARY 1 AND 2, 1989

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1. The current policy of notifying the public of the availability of information on technical topics, like MISA regulations, and awaiting input has led to a very low response rate from the public, if special pressure groups are excluded.

2. The participants felt that, generally, the Ministry's viewpoints were distrusted and not accepted by the public.

3. The proposed new MOE policy on public consultation requires a two-way flow of information with the expectation that the public can affect the Ministry's decisions.

4. For this to occur, involvement by the public, exclusive of organized and active groups, must be increased or, alternatively, the public must be educated so it can understand and maybe accept the way the Ministry proceeds in setting standards.

5. Therefore, the participants felt that a major public education program about the Ministry's standard setting procedures should be undertaken. This program may be considered a "major program initiative" as stated on p.3 of the new public consultation policy document.

   The need for education about standard setting was stressed in the public response to the ACES discussion paper.

6. The aims of the public education program are:

   - to educate the Ministry, the Advisory Committee on Environmental Standards (ACES) and the public on different standard setting processes.
   - to increase the trust in and credibility of the Ministry.
   - to increase the acceptance by the public of the Ministry's standard setting procedures.

7. To accomplish this, it is necessary to find out what information and in what format the various sectors of the public wish to have. Consultation with ACES and the public is necessary to be able to target the appropriate information to the proper audiences.

8. The public participation process for ACES can then consist of sending technical information for standard setting only to those interested in receiving it and more general information packages to other segments of the public.

9. An additional advantage of the education process is that all of the Ministry standard setting processes will have to be clearly articulated. A committee representing all the relevant branches can be set up for this task. The end product of this committee's work would be a document that:

   - explained the advantages and disadvantages of each process.
   - explained the reasons for the differences.
   - explained how the standard/guideline numbers are arrived at and how the standard setting process can be enforced and strengthened through the Control Order and Certificate of Approval procedures.

10. The disadvantage of the education approach are:

   - the process is lengthy.
   - ACES may not be the right vehicle for sponsoring the education of the public.
   - education of the public does not necessarily lead to the public accepting the viewpoint of MOE.
   - to be successful, this approach requires the commitment of sufficient resources and the development of a communications plan.

11. To increase the credibility of the standard setting process and of ACES, the participants felt that preferably all and certainly the non-technical members on the committee should be chosen by the stakeholders to act as their representatives.

J.J. SMITH AND K. ROBERTS

CLOSING REMARKS

CLOSING REMARKS:

J.J. SMITH
HAZARDOUS CONTAMINANTS COORDINATION BRANCH
AND
K. ROBERTS
WATER RESOURCES BRANCH

THIS WORKSHOP WAS SET UP TO FULFILL THE FOLLOWING THREE OBJECTIVES:

1. NETWORKING
   A) STAFF
   B) UNDERSTANDING PROCESSES

2. IDENTIFICATION OF COMMON ISSUES AND HURDLES

3. INTEGRATION AND HARMONIZATION OF PROCESSES

I WOULD LIKE TO SPEND THE NEXT FIVE TO TEN MINUTES TO DISCUSS WHETHER THESE OBJECTIVES WERE MET AS DETERMINED BY KEN ROBERTS AND MYSELF.

1. <u>NETWORKING</u>

1A) <u>NETWORKING AMONG STAFF</u>: IT IS OUR OPINION THAT THE WORKSHOP HAS FULLY MET THIS OBJECTIVE. THE APPROXIMATELY 50 INDIVIDUALS AT THIS WORKSHOP DEVELOP STANDARDS, GUIDELINES, OBJECTIVES, AND CRITERIA FOR THE PROTECTION OF HUMAN HEALTH AND THE ENVIRONMENT. IN ESSENCE, COLLECTIVELY YOU MAKE MAJOR DECISIONS THAT EFFECT THE QUALITY OF THE ENVIRONMENT IN THE PROVINCE TODAY AND IN THE FUTURE. THIS WORKSHOP HAS ALLOWED YOU TO MEET EACH OTHER, BEGIN TO UNDERSTAND THE VARIOUS PROCESSES AND TO MAKE SOME RECOMMENDATIONS TOWARDS SOLVING SOME VERY DIFFICULT PROBLEMS THAT WE ALL FACE.

1B) NETWORKING AND UNDERSTANDING THE STANDARD SETTING PROCESSES: DURING THE FIRST DAY, WE HEARD FROM A NUMBER OF SPEAKERS COVERING MANY OF THE STANDARD SETTING PROCESSES IN THE MINISTRY. THE FOLLOWING PROCESSES WERE DISCUSSED IN DETAIL AND GREATLY INCREASED THE LEVEL OF UNDERSTANDING OF THE GROUP:

- AIR ORIENTED STANDARD SETTING:
  - ° HUMAN COMPONENT
  - ° PLANT/SOIL COMPONENT*
- WATER ORIENTED STANDARD SETTING:
  - ° DRINKING WATER
  - ° SURFACE WATER QUALITY
- WASTE ORIENTED STANDARD SETTING
  - ° LISTING/DELISTING
- MULTI-MEDIA ORIENTED STANDARD SETTING

STANDARD SETTING PROCESSES THAT WERE NOT ADDRESSED OR WERE ADDRESSED BUT FOR WHICH INSUFFICIENT INFORMATION WAS PROVIDED ARE:

- AIR ORIENTED STANDARD SETTING
  - ° TERRESTRIAL COMPONENT - NON-HUMAN AND NON-PLANT
- WATER ORIENTED STANDARD SETTING
  - ° SEDIMENT COMPONENT
  - ° FISH CONSUMPTION COMPONENT
- WASTE MANAGEMENT ORIENTED STANDARD SETTING
  - ° DECOMMISSIONING COMPONENT
  - ° SLUDGE UTILIZATION COMPONENT.

IT IS RECOMMENDED THAT THESE TOPICS BE ADDRESSED THROUGH FUTURE WORKSHOPS.

* INFORMATION SUBMITTED AS ADDENDUM TO SPEAKERS PRESENTATION.

2. IDENTIFICATION OF COMMON ISSUES AND HURDLES

THE MAJOR RECOMMENDATIONS WITH RESPECT TO COMMON ISSUES AND HURDLES FOR CONSIDERATION BY THE STANDARDS STEERING COMMITTEE ARE TO:

- DEVELOP COMMON TERMINOLOGY;
- DEVELOP A COMMON "MASTER LIST" FOR THE HAZARD IDENTIFICATION PROCESS;
- EVALUATE UNCERTAINTY FACTOR AND CARCINOGEN CLASSIFICATION SCHEMES;
- DEVELOP GUIDELINES FOR MINIMUM DATA PACKAGE;
- REVIEW TERRESTRIAL (NON-PLANT) ACTIVITIES AND ROLE IN MINISTRY;
- REVIEW THE APPLICATION OF MUTAGENICITY TESTING AND INTERPRETATION TO OTHER AREAS;
- EXAMINE THE USE OF "ECOSYSTEM APPROACHES" TO STANDARD SETTING;
- DEVELOP GENERIC PROTOCOLS FOR STANDARD SETTING;
- DEVELOP A CENTRAL REGISTRY FOR STANDARDS AND FOR INFORMATION USED IN STANDARD SETTING;
- DEVELOP A CONSENSUS ON WHAT IS A MULTI-MEDIA CONTAMINANT; AND
- REVIEW THE USE OF PRIVATE SECTOR CONSULTANTS.

3. INTEGRATION AND HARMONIZATION OF PROCESSES

TWO APPROACHES CAN BE TAKEN - TOP DOWN AND BOTTOM UP. THIS WORKSHOP HAS TAKEN A BOTTOM UP APPROACH WHEREBY KEY ACTIVITIES WITHIN EACH OF THE PROCESSES ARE HARMONIZED/ INFLUENCED IN A MANNER THAT SHOULD FORCE THE INDEPENDENT PROCESSES INTO AN INTEGRATED MODE. KEY ACTIVITIES WHICH WOULD ACCOMPLISH THIS ARE THE DEVELOPMENT OF COMMON SCIENTIFIC PRINCIPALS AND A COMMON INFORMATION DATABASE.

FOLLOW UP

A FOLLOW UP ACTION PLAN IS PROPOSED AS FOLLOWS:

- PAPERS AND WORKING GROUP SUMMARIES TO R. WEILER BY FEBRUARY 16;

- STANDARD STEERING COMMITTEE MEETING TO DISCUSS RECOMMENDATIONS (WORKING GROUP LEADERS TO BE INVITED) - MARCH/APRIL

- FEEDBACK TO ATTENDEES - APRIL

ON BEHALF OF THE STANDARDS STEERING COMMITTEE, KEN AND I THANK YOU FOR YOUR PARTICIPATION AND HOPE THAT THIS HAS BEEN AS MUCH AS A POSITIVE EXPERIENCE FOR YOU AS IT HAS BEEN FOR THE COMMITTEE MEMBERS.

APPENDIX A

WORKSHOP PROGRAM

PROGRAM

WORKSHOP ON STANDARD SETTING PROCESSES IN THE ONTARIO MINISTRY OF THE ENVIRONMENT

FEBRUARY 1-2, 1989

Objectives

1. To increase the understanding among staff of MOE's standard setting processes
2. To identify common hurdles and issues
3. To develop recommendations for Ministry-wide guidelines for harmonizing standard setting processes

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Day One

Session Chairman: J.J. Smith

Time	Topic	Responsibility
9:00	Welcome	J.W. Giles/D. Balsillie
9:15	Reg. 309 and Waste Management	R. Breeze/R. Khettry, D. Crump/W. Ng
10:00	Environmental Air, Soil and Vegetation Standards	G. Nagy
10:30	Coffee Break	
10:50	Setting Aquatic Environmental Objectives and Guidelines	J. Ralston/C. De Barros
11:35	Drinking Water Objectives - An Example of Federal-Provincial Cooperation	A. Vajdic
12:05	Multi-Media Standard Setting - from Risk Identification to the Scientific Criteria Document	A. Socha/G. Jenkins
12:35	Lunch	
1:45	Public Consultation in the Standard Setting Process, and the Advisory Committee on Environmental Standards (ACES)	R. Weiler
2:15	Assignment of Working Groups; Coffee Break	
2:30	Small Group Discussions	
5:00	Recess	

Day Two
Session Chairman: K. Roberts

Time	Topic	Responsibility
8:30	Discussion Leaders and Rapporteurs prepare to report to discussion groups	
9:30	Discussion Leaders finalize discussions with group, and prepare to report to Plenary Session	
10:15	Coffee Break	
10:30	Reports to Plenary Session:	
	10:30 - Risk Identification	A. Vajdic
	11:00 - Risk Assessment, Humans	A. Szakolcai
	11:30 - Risk Assessment, Other Organisms	S. Abernethy
	12:00 - Integrated Standard Setting	B. Thorpe
12:30	Lunch	
1:45	Reports to Plenary Session: Public and Peer Review	R. Weiler
2:15	Summary and Recommendations	J.J. Smith/K. Roberts
2:35	Adjournment	

APPENDIX B

LIST OF PERSONS INVITED TO ATTEND

ATTENDEE LIST

AIR RESOURCES BRANCH

L. Shenfield Assistant Manager	Emission Technology and Regulation Development 880 Bay Street, 4th floor
John Hewings, Supervisor	Regulation Development and Environmental Assessment 880 Bay Street, 4th floor
D. McIlveen, Supervisor	Diagnostic Unit 880 Bay Street, 3rd floor
G. Nagy, Coordinator	Standard Setting 880 Bay Street, 4th floor
R. Pearson, Manager	Phytoxicology 880 Bay Street, 3rd floor
A. Szakolcai, Coordinator	Air Contamination Evaluation 880 Bay Street, 4th floor
R. Rinne, Supervisor	Soils & Vegetation Assessment 880 Bay Street, 3rd floor
D. Harper	Controlled Environment Brampton

WASTE MANAGEMENT BRANCH

D. Crump, Manager	Special Waste & Information Support 40 St. Clair Avenue West, 5th floor
G. Castonguay, Senior Engineer	Special Waste & Information Support 40 St. Clair Avenue West, 5th floor
R. Khettry, Supervisor	Hazardous Waste Listing/Delisting Special Waste & Information Support 40 St. Clair Avenue West, 5th floor
R. Dalrymple, Supervisor	Industrial Waste Management 40 St. Clair Avenue West, 5th floor
W. Ng, Supervisor	Waste Processing & Destruction Technology 40 St. Clair Avenue West, 6th floor
S. Radcliffe, Senior Industrial Waste Management	Industrial Waste Management 40 St. Clair Avenue West, 5th floor

Attendees, continued.....

WATER RESOURCES BRANCH

J. Ralston, Manager	Aquatic Biology Section 1 St. Clair Avenue West, 4th floor
N. Bazinet, Scientist	Contaminant Assessment Aquatic Biology Section 1 St. Clair Avenue West, 4th floor
C. deBarros, Specialist	Contaminant Assessment Aquatic Biology Section 1 St. Clair Avenue West, 4th floor
P. Dennis, Coordinator	Water Quality and Policy, MISA 1 St. Clair Avenue West, 4th floor
C. Neville, Scientist	Vertebrate Toxicology Aquatic Biology Section 1 St. Clair Avenue West, 4th floor
W. Scheider, Supervisor	Bioassessment Unit Aquatic Biology Section 1 St. Clair Avenue West, 4th floor
G. Westlake, Supervisor	Aquatic Toxicity Unit Aquatic Biology Section 1 St. Clair Avenue West, 4th floor
S. Abernathy	Aquatic Biology Section 1 St. Clair Avenue West, 4th floor
K. Roberts, Manager	Drinking Water Section 1 St. Clair Avenue West, 3rd floor
H. Graham, Physical/ Biological Quality Specialist	Drinking Water Section 1 St. Clair Avenue West, 3rd floor
P. Lachmaniuk, Drinking Water Assessment Specialist	Drinking Water Section 1 St. Clair Avenue West, 3rd floor
C. Sackville-Duyvelshoff, Program Development Officer Policy/ Assessment	Drinking Water Section 1 St. Clair Avenue West, 3rd floor
A. Vajdic, Supervisor Policy/Assessment	Drinking Water Section 1 St. Clair Avenue West, 3rd floor

Attendees, continued.....

HAZARDOUS CONTAMINANTS COORDINATION BRANCH

J.J. Smith, Manager	Standards Development Section 40 St. Clair Avenue West, 7th floor
B. Thorpe, Supervisor	Risk Assessment Unit Standards Development Section 40 St. Clair Avenue West, 7th floor
B. Birmingham, Standards Coordinator	Risk Assessment Unit Standards Development Section 40 St. Clair Avenue West, 7th floor
G. Jenkins, Standards Coordinator	Risk Assessment Unit Standards Development Section 40 St. Clair Avenue West, 7th floor
B. Leece, Assistant Standards Coordintor	Risk Assessment Unit Standards Development Section 40 St. Clair Avenue West, 7th floor
S. Fleming, Assistant Standards Coordintor	Risk Assessment Unit Standards Development Section 40 St. Clair Avenue West, 7th floor
E. Leggatt, Supervisor	Risk Identification Unit Standards Development Section 40 St. Clair Avenue West, 7th floor
R. Macfarlane, Scientific Information Coordinator	Risk Identification Unit Standards Development Section 40 St. Clair Avenue West, 7th floor
K. Johnson, Priority Contaminant Coordinator	Risk Identification Unit Standards Development Section 40 St. Clair Avenue West, 7th floor
A. Socha, Environmental Scientist	Risk Identification Unit Standards Development Section 40 St. Clair Avenue West, 7th floor
R. Weiler, Executive Secretary	Advisory Committee on Environmental Standards Standards Development Section 40 St. Clair Avenue West, 7th floor
P. Muller, Standards Coordinator	Risk Assessment Unit Standards Development Section 40 St. Clair Avenue West, 7th floor

Attendees, continued.....

COMMUNICATIONS BRANCH

D. Evans, Manager	COA Information Officer Public Information and Consultation 135 St. Clair Avenue West, 6th floor

REGIONAL

Southwestern Region

D. Huber, Regional Hydrologist and Assoc. Surface Water Eval.	Technical Support Section London
R. Griffiths	Technical Support Section London

West Central Region

R. Stewart	Technical Support Section Hamilton

MINISTRY OF LABOUR

J. Stopps, Chief	Policy & Regulations Branch Health Studies Service 400 University Avenue, 8th floor
E. McCloskey, Supervisor	Scientific Unit Policy & Regulations Branch Health Studies Service 400 University Avenue, 8th floor
T. Stopps, Scientific Consultant	Policy & Regulations Branch Health Studies Service 400 University Avenue, 8th floor
B. Worthington, Scientific Consultant	Policy & Regulations Branch Health Studies Service 400 University Avenue, 8th floor

Attendees, continued.....

Ministry of Labour, continued

A. Alexiadis, Scientific Consultant	Policy & Regulations Branch Health Studies Service 400 University Avenue, 8th floor
B. de France, Scientific Consultant	Policy & Regulations Branch Health Studies Service 400 University Avenue, 8th floor
T. McGrath	Health & Safety Services Branch Health Studies Service 400 University Avenue, 8th floor

DEPARTMENT OF NATIONAL HEALTH & WELFARE

M.E. Meek	Monitoring and Criteria Division Environmental Health Centre Tunney's Pasture Ottawa, Ontario K1A 0L2

APPENDIX C

DISCUSSION GROUP LEADERS AND RAPPORTEURS

DISCUSSION GROUP LEADERS AND RAPPORTEURS

RISK IDENTIFICATION - A. Vajdic, A. Socha

RISK ASSESSMENT: HUMANS - A. Szakolcai, B. Leece

RISK ASSESSMENT: OTHER ORGANISMS - S. Abernathy, K. Johnson

INTEGRATED STANDARD SETTING - B. Thorpe, B. Worthington

PUBLIC PARTICIPATION AND THE ADVISORY COMMITTEE ON ENVIRONMENTAL STANDARDS - R.R. Weiler, D. Evans

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